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AGENT ORANGE STUDIES

HEARING

BEFORE THE

SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE

OF THE

COMMITTEE ON VETERANS' AFFAIRS HOUSE OF REPRESENTATIVES

NINETY-NINTH CONGRESS

SECOND SESSION

JULY 31, 1986

Printed for the use of the Committee on Veterans' Affairs

Serial No. 99-58

U.S. GOVERNMENT PRINTING OFFICE

64-331 O WASHINGTON : 1986

For sale by the Superintendent of Documents, Congressional Sales Office
U.S. Government Printing Office, Washington, DC 20402

H761-33

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AGENT ORANGE STUDIES

THURSDAY, JULY 31, 1986

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, D.C.

The subcommittee met, pursuant to notice, at 9:06 a.m., in room 334, Cannon House Office Building, Hon. Bob Edgar (chairman of the subcommittee) presiding.

Present: Representatives Edgar, Daschle, Evans, Kaptur, Penny, Rowland of Georgia, Hammerschmidt, Solomon, Smith of New Jersey, Ridge, and Rowland of Connecticut.

OPENING STATEMENT OF CHAIRMAN EDGAR

Mr. EDGAR. The subcommittee will come to order.

Thirteen times since 1978 the House Veterans' Affairs Committee and its subcommittees have held hearings on the subject of Agent Orange. Here we are again.

Being one of the original members of this committee to call for those first hearings in the late 1970s, I have to admit that this 9-year process has been one of the most frustrating experiences in my tenure on this committee. Every time we think we have made a step forward in resolving the Agent Orange question, something always happens to push us two to four steps backwards.

Sometimes science and scientists have been the stumbling blocks; sometimes policy and policymakers have been the problem; and sometimes the two get so mixed up that it is impossible for us to tell whether Agent Orange is really an unsolveable problem or a problem nobody really wants to solve.

Over the past few months we have been hearing consistent reports that the major Agent Orange study mandated by this committee and the Congress in 1979 was in serious trouble. We heard that a recommendation from a White House science panel had been forwarded to the Agent Orange working group declaring the protocol for the study scientifically is unfeasible.

Then we heard nothing, and we heard nothing, and we heard nothing.

So we called for these hearings today to get a straight answer from the administration for the sake of all of those Vietnam veterans who expect and deserve that answer.

We asked to hear from Dr. Alvin Young, past Chair of the White House science subpanel that made the recommendation to the working group. Dr. Young, who has testified many times before this committee, declined to testify today.

We asked to see a copy of Dr. Young's report, and we were told by the White House, or the Office of Management and Budget, that they would not let us have a copy of that report.

We invited Don Newman, Under Secretary of the Department of Health and Human Services, and chairman of the Agent Orange working group, to testify today to tell us what policy decisions are to be made based on the science panel's recommendations. If the protocol for the study is unworkable, then how does this administration propose to fulfill the mandate of the Congress and complete the study. But, Mr. Newman declined to testify as well.

No one expected the study to be easy. We did expect, however, that the major players would keep us informed of its problems and its progress. The Congress authorized this study in 1979. It is now 1986. It appears that we are no further along after all this time, and all these dollars spent in getting this study underway, than we were 8 years ago.

The Vietnam veterans of this country deserve better efficiency on the part of their Government than that. They deserve a better show of good faith than this.

I remember in 1982 sitting in this hearing room in a similar circumstance. It wasn't the Department of Health and Human Services or the Centers for Disease Control who had dropped the ball on the study. It was the Veterans' Administration that had the initial shot at it all. There was a question about who was dragging their feet on the Agent Orange question then.

The response, ironically, came from one of our witnesses today. On September 12, 1982, Dr. Vernon Houk of the Centers for Disease Control responded this way: "If we were responsible for the development of the protocol, I would get a group of people, epidemiologists, laboratory people, the necessary ones from our own shop, and outside help if we had to have it . . . put them all in a room and tell them not to come out until they had this protocol done. That would take, in my estimation, maybe a couple of weeks."

That was 4 years ago. After 4 years, there is still a lot of people locked up in a room somewhere downtown, or somewhere in this country, with nothing to show for it. Hopefully, this hearing today will answer some of those questions—the question of where we are on this study, the question of where we need to go to make sure that the answers that have been sought are provided to the Vietnam veterans of this country.

There are three areas that I hope to cover in my questioning: First, what is the current status of the CDC protocol for the Agent Orange study; second, what does the special science subpanel recommendation that the Agent Orange study not go forward based only on the Army personnel records really mean; and third, how much money has been expended on Agent Orange so far, on studying it, on trying to analyze it, and what do we have to show for the money we have spent. Those will be the three areas of my questioning as we listen to the witnesses today.

I now yield to my colleague, the ranking minority member of the full committee and subcommittee, the Honorable John Paul Hammerschmidt.

[The prepared statement of Mr. Edgar appears on p. 47.]

OPENING STATEMENT OF HON. JOHN PAUL HAMMERSCHMIDT

Mr. HAMMERSCHMIDT. Thank you very much, Mr. Chairman.

The Agent Orange study being conducted by the Centers for Disease Control, of course, has generated great interest. This committee wants to have a scientifically valid and credible study to get to the bottom of the question about Agent Orange.

I know it's asking a lot of some Members, especially in an election year, that the study should be kept above partisanship, as has been the tradition of this committee over the 20 years I have served on it, and before that. I believe there are some basic questions which our witnesses should answer for us at today's hearing on the conduct of the Agent Orange study mandated by Public Law 96-151.

What is the current status of the Agent Orange study? It has been stated that the administration wants to scrap it. Is this true? Just what has been the role of the administration? Has it in any way interfered in the scientific aspect of the study? Further, what can we expect as to the future?

We know there have been some scientific obstacles encountered in developing an exposure index. We don't want to rush the study, but unnecessary delays, of course, should be avoided.

Mr. Chairman, in my view, there is enough anxiety about Agent Orange without having a second set of anxieties about how the study is being conducted. Members of this subcommittee and of the full committee certainly want to do everything they can to keep the study on track. We have some highly respected scientists with us this morning. I look forward to hearing from them.

I regret that I am going to have to go to an Aviation Subcommittee markup in about 30 minutes, so I may not have the opportunity to hear all of our witnesses. But I will certainly go over their testimony carefully.

Thank you very much, Mr. Chairman.

Mr. EDGAR. Thank you.

Before hearing from our first witness, I would like to ask unanimous consent to enter into the record at this point two letters from the Department of Health and Human Services. Both letters are addressed to me as the Chair of this Subcommittee on Hospitals and Health Care. One is from Robert L. Racklin, chair pro tem of the Agent Orange Working Group, and the other is from Ronald F. Docksai, Assistant Secretary for Legislation. I would ask that both of these letters be included in the record at this time.

Without objection, so ordered.

[The letters appear on pp. 55 and 56.]

Mr. EDGAR. I yield to my colleague, Mr. Rowland.

Mr. ROWLAND OF CONNECTICUT. Thank you, Mr. Chairman.

Congressman Ridge from Pennsylvania is delayed in getting here, and I would like to ask unanimous consent to put his opening statement in the record.

Mr. EDGAR. Without objection, so ordered.

Mr. ROWLAND OF CONNECTICUT. Thank you, Mr. Chairman.

[The statement of Hon. Thomas J. Ridge appears on p. 57.]

Mr. EDGAR. Are there any other opening coments?

Let us move now to hear from our first witnesses, the Honorable Don Bonker from the Third District of Washington. Don, it is a pleasure to have you here this morning and we look forward to your testimony.

STATEMENT OF HON. DON BONKER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WASHINGTON

Mr. BONKER. Thank you, Mr. Chairman. I appreciate the opportunity to appear with my distinguished colleague, Mr. Wirth, before your panel. I know we speak on behalf of hundreds of our colleagues who have concern over this administration's policy with respect to problems associated with Agent Orange.

Mr. Chairman, I have a statement that I would like to submit for the record.

Mr. EDGAR. Without objection, the full text of your statement will be made a part of the record. You may proceed.

Mr. BONKER. Mr. Chairman, my district office has been heavily involved with a very active veterans group in Washington State, veterans who are, indeed, suffering and who have only had limited access to relief or assistance from the Veterans' Administration.

I have organized several meetings between these veterans groups and the Veterans' Administration. Yet the response from the three regional hospitals to to the problems that these men have as a result of their service in Vietnam has not been completely satisfactory. And because of these problems, I have attempted to elevate these concerns at the national level, and that is why I am so terribly pleased with the work you have done in this committee, not only in laying the groundwork for the laws that are now in place, but to continue to monitor various activities to see why we don't have the answers that everybody seeks with respect to Agent Orange.

I really don't know what the problem is. The Veterans' Administration is there to help veterans who have service-related disabilities or problems. I don't know if it's an attitudinal problem with respect to this administration or whether it's a matter of spending reductions and budgetary considerations, or perhaps it's just inefficiency. But I think these young men and women who served so valiantly in what has become an unpopular war deserve better treatment.

The concerns that I have expressed in my formal statement, Mr. Chairman, deal a lot with the process of how we determine whether or not Agent Orange is responsible for many of the diseases that afflict veterans today. But while they suffer from life-threatening physical problems, they have had to endure a 7-year wait while the Federal Government attempts to deal with this problem and come up with answers.

They are particularly angered that the Centers for Disease Control provided the assurances, as you noted in your statement, over 3 years ago when they took over this study from the VA, that they would have no problem in completing the study and coming up with some answers. And yet, over all, there has been a 7-year delay.

I don't know whether the Center, which has a very good reputation, lacks the professional capability in this case, or again, perhaps it's a matter of budget considerations, or just determining priorities. I will be looking forward today to their testimony and your tough questions to see exactly what the problem is, so that we in the Congress and the veterans' organizations who we represent have some answers.

Mr. Chairman, I am particularly concerned about the design problems associated with the study and with CDC's work concerning the Army's environmental support group that have come to light since last winter, and the unresponsiveness of the CDC to the concerns of Congress with respect to the protocol study. So I am hopeful that this committee will be able to obtain from the witnesses that will be appearing before you today the answers that will put to rest some of these disturbing questions. Hopefully you will be looking at the issue of the cost of the study, the reliability of any proposed alternative protocol, and whether the CDC is using the Agent Orange study money to further research in other areas—which I hope is not the case.

Lastly, Mr. Chairman, I would like to submit the question and testimony prepared by one of my constituents, Mr. Joe Cole, who represents the Agent Orange Committee of the Washington State Council of the Vietnam Veterans of American. Perhaps this committee could provide these questions to the various witnesses for written response later on. Mr. Cole has been very active in this group and is informed on the issue.

Mr. EDGAR. Without objection, his statement will be made a part of the record, and we will make that available to the witnesses.

[The statement appears on p. 63.]

Mr. BONKER. In closing, Mr. Chairman, I want to again thank you and Mr. Daschle and other members of this committee for your vigilance on this issue. I know it is not an easy one to deal with, but I am really convinced that this committee is the last hope for veterans throughout this country who are suffering and who need the support.

I really feel that it's an affront to these veterans, who have already suffered enough for their heroic service, in what has become an unpopular war. So I think the least we can do is provide the medical treatment and the assistance to which they are fully entitled by our Government.

Thank you, Mr. Chairman, for the opportunity to testify.

[The statement of Hon. Don Bonker appears on p. 58.]

Mr. EDGAR. Thank you.

Before we move to questions, I wonder if my colleague, the Honorable Tim Wirth, could give his statement. Then I will open it to questions from our members.

Tim, it is a pleasure to have you here. We look forward to hearing from you. The full text of your statement, without objection, will be made a part of the record.

STATEMENT OF HON. TIM WIRTH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Mr. WIRTH. Thank you very much, Mr. Chairman. I do have a full statement and I would appreciate your including that in the record.

Mr. Chairman, 12 years ago you came to the Congress; 12 years ago Congressman Bonker came to the Congress; and 12 years ago I came to the Congress. I remember early in our first session here discussing the plight of Vietnam veterans, the fact that, for them, "Johnny did not come marching home" as had happened in our national experience before, and the fact that all of us had an obligation to meet our responsibilities as a nation to those people who had valiantly and patriotically fought in Vietnam.

Clearly, the Agent Orange situation is a vestige of that very same problem. We would not be here today had the administration met its responsibilities to those veterans who were exposed to Agent Orange.

Seven years ago, as Congressman Bonker pointed out, 7 years ago you and Congressman Daschle and Congressman Bonker and I all sponsored the requirement that the study be undertaken. Now, 7 years later, amazingly enough, the administration is trying to abdicate their responsibilities entirely, to try to duck the responsibility and to say that this study is scientifically unworkable.

Now, Mr. Chairman, you know and I know that's preposterous. For them to be saying they did not have a large enough sample simply ignores the facts of exposure to Agent Orange. For them to be saying they can't do this when 15 States, Mr. Chairman, 15 States have undertaken a study, and the Federal Government finds that they can't do it, is absolutely ridiculous.

Now, I think Congressman Bonker asked the right questions, and you all are going to be pursuing that. I know this committee is the last hope. You will ask is this because the Centers for Disease Control doesn't have the capability? I think not. All of us know the Center for Disease Control is a very, very able and scientifically capable group. I believe it is simply the fact that the administration wants to duck and is attempting once again to attempt their own budget shenanigans on the backs of some of the most unfortunately impacted people in this society, in this case people who have been exposed to Agent Orange.

I would guess, when we get down to the bottom of it, the administration does not want to unearth the correlation between Agent Orange and the problems these individuals have had. It's a budget situation and, once again, what they're trying to do is to duck for the purposes of avoiding the problem.

That's pretty harsh. I realize that, Mr. Chairman. But I don't see that there's any other explanation that one can come to.

This is the last hope. We will do everything we can to help you. I again commend you for having this hearing and continuing to put the kind of pressure that you are and the kind of pressure that has to be placed on the administration to exercise their responsibilities to govern in the United States and not to duck yet another issue.

Thank you, Mr. Chairman.

[The statement of Hon. Tim Wirth appears on p. 71.]

Mr. EDGAR. Thank you. I want to commend both of you for your statements today and for taking the time to testify.

I would like to say that, as someone who has been involved in this particular issue since coming to Congress, and particularly with Don Edwards' participation in one of the first letters to this committee and to the administration to look at the issue, this is not a partisan issue; it's not an issue that we're just frustrated with this administration. There have been previous administrations we have also been frustrated with, one of which at least was a Democratic administration.

While I share your frustration at coming here 3 or 4 years after we took the study away from the VA and put it in the Center for Disease Control, there seems to be a difficulty by the Government itself in responding adequately to the problems faced by Vietnam veterans with exposure to Agent Orange. It is right for us to ask those tough questions, of why can't we study the causality between the use of the defoliant in Vietnam and the systemic diseases that many veterans are experiencing, and what you said, Mr. Bonker, about your aggressive groups in Washington State is not uncommon. In Colorado and Pennyslvania and other States the Vietnam veterans are sitting looking at the Government, not at an administration of a particular party, but just government itself, saying "Can't you do something to clarify the questions that have been raised over time, and can't you give us the answers that you set out to get in 1979, and here we are in 1986 without those answers."

It is really important and appropriate for us to hear from the Center for Disease Control and from other Government officials today, to find out why we haven't been able to get those answers. So I particularly appreciate both of you coming and asking the right questions of this panel and of Government in general.

I yield to my colleague, Mr. Ridge, for any questions he might have.

Mr. RIDGE. I have no questions. Thank you, Mr. Chairman.

Mr. EDGAR. Are there any questions from our colleagues?

Mr. ROWLAND OF CONNECTICUT. Mr. Chairman.

Mr. EDGAR. Mr. Rowland.

Mr. ROWLAND OF CONNECTICUT. Thank you, Mr. Chairman.

I would like to thank the gentlemen and commend them for their testimony and also their interest in the issue. I think we appreciate that, as well as your constituents.

I just, more out of curiosity than anything else, want to follow up with Congressman Wirth, when he made reference to the budget cuts. I think it's important for us to know, in trying to combat the problem and find some solutions, what the specifics are.

In your testimony you made reference to budget cuts affecting the studies that we're still waiting on. Can you give us some more details on that because we would like to be able to follow up on that.

Mr. WIRTH. Mr. Rowland, if you look at the requests that came in from the administration relating to the VA and veterans' programs in general, you see a broad pattern of attempting to cut back one place after another. If you've been around here for, I feel, as long as I have, you begin to look at patterns and you begin to understand the implications of Agent Orange are going to be pretty

severe—at least I happen to believe so, in talking to people in the district that I represent in the State of Colorado. The implications of this are going to be very severe. It's going to cost a lot of money to right this problem, not dissimilar from what happened to the members of the military that were exposed to nuclear problems right after World War II during the late forties and early fifties.

Those are going to require expenditures by the administration, by the VA, by the Congress, and if you're in a position of saying "Hey, we don't want to do that, we don't want to spend that kind of money; we have other priorities", then you're going to say let's not find there is a problem. I mean, that's a pattern that has existed for a long time, bury your head in the sand and say it isn't there.

I think Mr. Edgar is correct in pointing out the frustration that a lot of people feel with Government overall. I think that's very real. But in this situation, we've had 7 years now, Mr. Rowland, for these people to conduct this study, and now we're seeing that they're saying "Hey, we don't think this is scientifically workable."

What is that when 15 States can do the job? It seems to me it raises all kinds of questions.

Mr. ROWLAND OF CONNECTICUT. I agree with your comment, and maybe I misheard you when you testified, but I thought the reference in your testimony was made to the fact that the studies weren't being done because of budget cutbacks and I was wondering if you had any specific evidence or details of that.

Mr. WIRTH. I say that it's my belief for what's happening, that they are squeezing down on these studies and saying they're not scientifically workable for reasons of budget policy, not for reasons of scientific value.

Mr. ROWLAND OF CONNECTICUT. That's CDC saying that?

Mr. WIRTH. No. I would just suspect that that problem is coming from the administration.

Mr. ROWLAND OF CONNECTICUT. More of it is theory rather than reference to something specific?

Mr. WIRTH. I've been around long enough to look at these patterns, Mr. Rowland. You know, I'm deeply skeptical and, I would suggest, deeply suspicious.

Mr. ROWLAND OF CONNECTICUT. I agree with your comments about the future costs that would be incurred to combat the problem, and I appreciate that. I was just wondering if we needed on this committee to follow up on specific budget cuts or budgetary restraints that would affect those studies.

Mr. BONKER. Mr. Rowland, if I may be permitted a comment, we are all enduring budget reductions; I think that's one of the universal imperatives of our Government, given the sizeable deficits that we have. So there are going to be cutbacks across the board. Even if we do nothing, Gramm-Rudman will more or less dictate that reality.

I would be interested if you or the chairman could pose the question to Dr. Mason exactly what set of priorities are established by the Center for conducting its studies. Obviously, the Center has a great deal of work to do, there are many demands upon its time, and its professional staff can only go so far. At some point they have to establish priorities on what disease or problems warrant

their attention, and they must have a time frame within which to deal with some of these problems so they can be more conclusive in their work.

I would hope that the Center would take a sense of what the Congress says about this issue. This is a congressionally-mandated study. This is not something that's been brought in by one of the departments or a research exercise within the Center itself, but Congress has requested this study and we deserve to have an answer. It's the law of the land. If it is a lack of resources to conduct the study, then the Center should come before this committee and explain that fact.

So I would hope that when Dr. Mason appears you could pose that question, to see whether the Agent Orange question is way down their priority list or is it high. Then we could get a better sense of what the problem is.

Mr. WIRTH. If the gentleman would yield, in addition, on the subcommittee I have the privilege of chairing, we go back and ask various agencies what their original budget submission was and what they believed was necessary to do the job, what happened to that budget submission along the way, and what happened at OMB, and what is happening now in terms of execution, just to follow that flow of money.

If I'm wrong, Mr. Rowland—and I hope that I am wrong, on behalf of those veterans who have been impacted by Agent Orange—I truly hope that I am wrong. But I'll bet you will find out the squeeze, squeeze, squeeze is there because coming out of the other end of the pipeline is going to be a major set of financial problems that the administration is going to have to face.

Mr. EDGAR. I think, if the gentleman will yield——

Mr. ROWLAND OF CONNECTICUT. Certainly.

Mr. EDGAR. We're going to ask some of the budget questions of CDC in a little bit, to clarify whether or not the dollars are adequate to do the study and whether any of the delay and stumbling have come with lack of resources.

My guess is, even with Gramm-Rudman, even with the cuts, even with all of the pressures that we put on, that that isn't the critical question of money. When the question of money comes is if the study is completed and if there is causality found between the problems that we're facing, that the cost to the Federal Government in terms of compensation for this as a service-connected, service-related illness has some very ominous questions in terms of what it costs the Federal Government to wage war in Southeast Asia and what it cost in terms of the lives and the families that are involved.

Now, that's just speculation on my part, but I have seen in some of the discussions we have had earlier that there had been some fear early on by previous administrations and this one that if you actually make that determination, if it comes out that, in fact, higher illnesses are related to Vietnam, that the Federal Government would have to pay that cost. So we'll have to ask the question about whether or not adequate dollars are available for the study. My suspicion is it's not a dollar question in terms of the crunch of the study. I think the dollar question is what happens if the study or studies determine——

Mr. BONKER. Mr. Chairman, that's an important distinction. But it seems to me the Center, as a professional institution, has to deal with the health-related question and somebody else is going to have to deal with the compensation question. But there is no reason, no justification, to withhold the study because we fear down the road there's going to be a compensation issue. I would hope that the Center could separate those two issues and conduct its professional work on the study, and if the study has integrity and it has a conclusion that means more spending later on, then that's up to the Congress and the President to deal with.

Mr. ROWLAND OF CONNECTICUT. Thank you very much.

Thank you, Mr. Chairman.

Mr. EDGAR. Are there any other questions before we move on to our first witness?

Thank you very much for your testimony. We appreciate your coming.

The gentleman from Pennsylvania is invited to make a second brief opening statement. His first has been put in the record by his colleague, Mr. Rowland.

We invite Dr. Mason and those who are accompanying him to the table. I yield to my colleague, Mr. Ridge.

OPENING STATEMENT OF HON. THOMAS J. RIDGE

Mr. RIDGE. I thank the gentleman very much for yielding. I just wanted to add a few comments to those that have been made by my colleagues who previously testified.

I think it is important to get some perspective on the hearing today, that the congressional request for the study was initiated before this administration took office, and that the full impact of any completed study, whether it opens the doors wide for proper and adequate fair compensation, will be felt after this administration leaves office. So the comments with regard to some kind of clandestine effort of this administration to sidetrack this particular study—which it neither initiated and which it is not going to be around to implement—I think are somewhat misleading.

Secondly, Mr. Chairman, I think it is important to note that Congress itself, through the Office of Technology Assessment, has expressed a concern about the methodology of the study. That is one reason we are here today, and that is one reason I do commend my colleague, the gentleman from Pennsylvania, because I think there are very important and relevant issues that have to be discussed. One, indeed, is the 7-year delay, and coming up with a protocol to establish a medical link to determine the impact of the spread of this chemical agent on men and women who served in Vietnam.

I don't know if I was exposed to it. I have seen some maps that identify areas in Vietnam where there was heavy spraying done. My area of operation I haven't seen included specifically in any of those maps. So there is a lot of uncertainty among veterans as to whether or not they were exposed to it. The 15 State efforts that were referred to in the previous testimony, as I understand, involve more an effort to reach out and invite veterans who believe they may have been exposed to it, to contact their State government so they can have a list of potential victims, and I think that is a good

effort. But to say there are 15 States out there trying to accumulate scientific data I think is somewhat misleading because I'm not aware of any effort of any State to do that.

Finally, I would just say, from very practical experience that I would share with my colleagues on the committee, that 7 years is too long. I'm glad that you, Mr. Chairman, have brought this issue before this committee. I think it is too long. But I do recognize the difficulty, some difficulty, in trying to establish the physical presence of men and identifying the periods of time they were in areas that were identified to have been sprayed, the duration of their stay in the field, the amount of spraying and contaminant that was involved in the area, the correlation of those logistical matters over a 7- or 8-year period, as troops moved in and out of different areas of operation in Vietnam, was not a task easily undertaken.

However, I would say to my chairman that I think 7 years is sufficient time for them to be able to make that correlation. But I just wanted to set the record straight with regard to this administration's involvement and the not-so-subtle accusation that the squeeze to sidetrack this has come from the administration. It was not initiated under this administration, and the full effect will not be felt until this administration leaves. There is no proof—there is some innuendo and some inference—but I would be very interested to see if we can identify someone in this administration turning the money faucet off to deny the Center for Disease Control the opportunity to complete its study. It seems to me it's a logistical problem, a protocol problem, and I commend you, on behalf of all Vietnam veterans in Pennsylvania and throughout this country for conducting this hearing.

With that, I conclude my very brief remarks. Thank you, Mr. Chairman.

Mr. EDGAR. Your brief remarks will be added to your other brief remarks that were put in the record at the beginning.

Dr. Mason, it is a pleasure to have you before our committee today. We appreciate your patience in listening to our concern. We would hope that as we listen to your testimony that we can express ourselves on the issues and questions that we have raised.

I would hope, before you begin your statement, you would introduce those who accompany you. Thank you for coming.

STATEMENT OF JAMES O. MASON, M.D., DIRECTOR, CENTERS FOR DISEASE CONTROL, U.S. PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES; ACCOMPANIED BY EDWARD WEISS, ACTING EXECUTIVE SECRETARY, AGENT ORANGE WORKING GROUP; VERNON HOUK, DIRECTOR, CDC'S CENTER FOR ENVIRONMENTAL HEALTH; AND CARL KELLER, CHAIRMAN, AGENT ORANGE SCIENCE PANEL

Dr. MASON. Good morning. I am honored to be here representing Secretary Otis Bowen and Under Secretary Newman, who serves as Chairman of the Domestic Policy Council Agent Orange Working Group. I am also delighted to be here as representing CDC.

With me this morning are Mr. Ed Weiss, who is here as acting Executive Secretary of the Agent Orange Working Group; Dr. Vern Houk, Director of CDC's Center for Environmental Health; and Dr.

Carl Keller, who has served as Chairman of the Agent Orange Science Panel.

CDC was assigned responsibility for the design and conduct of the studies in January 1983, by an interagency agreement with the Veterans' Administration. In May of 1983, CDC completed and submitted a draft research protocol for scientific review and comment by four groups: The Office of Technology Assessment, the Science Panel of the Agent Orange Working Group, the Health and Human Services Advisory Committee on Special studies Relating to the Possible Long-Term Effects of Phenoxy Herbicides and Contaminants, and CDC's own independent ad hoc review panel. So a protocol, based on information available at that time, had been submitted by CDC by 1983, the month of May.

The format of these studies was published in November 1983. It incorporated modifications suggested by the scientific reviewers and included three independent but related studies that together comprise the Agent Orange projects. These three studies are the Vietnam Experience Study, the Agent Orange exposure study, and the selected cancers studies. These three studies represent a comprehensive approach to evaluating the health of Vietnam veterans.

We were given preliminary approval by OMB to begin conducting these studies in May 1984. By August of that year, CDC awarded the first of what would eventually be 15 major contracts for data collection. The first health interviews of Vietnam veterans—a test of systems to identify, locate and collect data for the Vietnam Experience Study—was begun by September 1984. Data collection for the Vietnam experience and the selected cancers studies were begun on the effective date of OMB's final approval in January 1985, and are continuing.

Data collection for the Agent Orange exposure study was originally planned to begin in January 1986. I will explain later why that was not possible to be done.

But, in summary, I would like to report that two of the three studies being carried out by CDC—the Vietnam Experience Study and the selected cancers studies—are going very well and are on schedule, thanks to the excellent participation of the veterans and their service organizations.

With regard to the Agent Orange exposure study, this was designed specifically to evaluate possible health effects of exposure to Agent Orange herbicides by comparing the health of an exposed cohort of male, U.S. veterans, with an unexposed cohort. The two cohorts should differ in their exposure to herbicides in Vietnam, while other health risk factors would have to remain constant.

In the original approved study protocol, numerous problems were anticipated regarding the categorization of veterans with respect to herbicide exposure. The protocol that we developed soon after we were assigned the responsibility indicated that, since the proposed categorization procedures were untested, verification through pilot testing would be needed before a final decision to proceed with the full-scale study could be made.

The United States Army and Joint Services Environmental Support Group—I'll refer to them as ESG—has worked diligently and effectively in abstracting location data to identify potentially exposed and unexposed individuals for inclusion in the study. Using

this information, CDC prepared and submitted to the Office of Technology Assessment two reports on exposure assessment and for the Agent Orange exposure study, one in February 1985, and another in November 1985. These reports indicated that it was possible to identify relatively few veterans with probable heavy exposure using information available to the ESG.

Initially, I remind you, before the military records were evaluated, it had been anticipated that the difficulty would be 180 degrees different in finding unexposed individuals. This is why a third cohort was included in the initial study protocol, because we thought we would have difficulty finding unexposed, and it is has turned out to be just the opposite.

This exposure assessment problem led CDC to later consider treating exposure as a continuous variable. That protocol was rejected by the Agent Orange Working Group and OTA, so we had to then try other approaches.

Let me emphasize that the difficulties in assessing exposure are related to the scope and content of the military records, not the manner in which these military records were abstracted by the environmental support group. The records were designed for military purposes, not for the purposes of doing an epidemiological study. All available information from the military records is being used and was abstracted appropriately by Dick Christian's staff.

Beginning in January 1984, and continuing until just weeks ago, an intensive effort to separate exposed from unexposed veterans has been underway by the diligent and effective staff of the ESG, the science panel of the Agent Orange Working Group, and CDC. A subpanel of the Agent Orange science panel, which has been referred to earlier, was established specifically to look at this issues which had been identified by CDC and ESG.

The June 4, 1986 recommendation of the subpanel was—and I quote: "Any study of ground troops which is dependent upon military records for the ascertainment of exposure to herbicides should not be conducted without additional methods to verify exposure." That recommendation was consistent with information that had been disclosed earlier to us.

Well, rather than just giving up at that point—and that would have been the easy thing to do—CDC has suggested a method for verifying whether exposure to dioxin actually occurred in a cohort of Vietnam veterans classified as potentially exposed to Agent Orange by military records. This verification would compare the actual level of dioxin found in veterans' fat or blood with the military record exposure estimate.

CDC has been evaluating a method for measuring dioxin levels in blood. This evaluation will correlate dioxin levels in fatty tissue and in blood in individuals with little or no exposure and those with high levels of exposure to dioxin. This evaluation of the blood-fat level relationship will be completed and peer-reviewed by September. If there is a correlation in this relationship, it may be possible to conduct a validation study to determine whether military records can be used to produce the two cohorts necessary for a scientifically-sound Agent Orange exposure study.

If the correlation is positive, CDC and ESG will develop a protocol for this validation. It is expected that the protocol, its review

and final action by the Agent Orange Working Group and OTA, can be completed by the end of this year.

If the validation study indicates that it is scientifically possible to separate exposed from unexposed veterans, then the method for identification of the two cohorts will be included in the Agent Orange exposure study protocol to be evaluated by OTA and the Agent Orange Working Group. An Agent Orange exposure study cannot be undertaken—it isn't scientifically feasible to undertake it—if the validation study demonstrates that it is not possible to use military records to identify exposed from unexposed veterans.

The budget is the final area I will address. I will say, parenthetically, that CDC has received all the money we have asked for. There have been no reductions. The total in-house costs for fiscal year 1983 through 1986 for personnel, equipment, et cetera, are approximately $11.3 million which have been allocated across the three studies. This figure is an estimate since fiscal year 1986 is not yet complete.

The vast majority of the contractual obligations were made in fiscal year 1984 when the funds were made available. For the selected cancers study, the total contractual obligations to date are approximately $4.3 million; the Vietnam Experience Study contractual obligations are approximately $17 million; and the contractual obligations for the Agent Orange exposure study are about $26 million.

These funds for the Agent Orange exposure study have not yet been spent, since this component has not yet started. In addition to these costs and obligations, it will be necessary to pay the contractors about $2 million for the costs associated with keeping the Agent Orange exposure study on hold through September. It will be necessary to negotiate final settlement costs with the contractors if this study cannot be conducted.

In addition to the ongoing work by the Centers for Disease Control, I should mention that this administration has committed significant resources to resolving the health concerns of Vietnam veterans through other studies that are ongoing by the Veterans' Administration and the Department of Defense.

That completes my testimony, Mr. Chairman. We will be happy to answer any questions that you or the subcommittee may have.

[The statement of James O. Mason appears on p. 74.]

Mr. EDGAR. Thank you very much, Dr. Mason.

Let me ask you a funding question first—and I appreciate your final concluding comments about that. What is the overall budget of CDC?

Dr. MASON. For CDC or for Agent Orange?

Mr. EDGAR. No, for your whole agency.

Dr. MASON. Our whole agency is about $480 million, with money that is directly appropriated to us, plus other contractual agreements.

Mr. EDGAR. Is that at about what you requested, or is that below your request?

Dr. MASON. We're running approximately at request.

Mr. EDGAR. We have some offices in Philadelphia, NIOSH offices, that are being consolidated because of so-called funding cutbacks. If you're running at the request level, the question has been raised in

our region as to why those offices are being consolidated to Atlanta and from 11 to 3 or 10 to 3.

Dr. MASON. Mr. Chairman, I would assure you that those changes in the configuration of our NIOSH regions are not related to budget cuts. Dr. Miliar, the Director of the National Institute for Occupational Safety and Disease, came to me and said that in the past we gave three NIOSH staff to all ten regions, the workload by region is so different—and we have our Cincinnati offices close to the Philadelphia area—he said it makes a lot of sense from cost effectiveness and quality of health hazard evaluation if we centralized those people, so there is a better——

Mr. EDGAR. I don't want to argue with that, but they told us——

Dr. MASON. That's the reason for it. It's to do the job better.

Mr. EDGAR. They tell us that the Philadelphia office, which is very busy and very good, is moving to Atlanta and not to Cincinnati, and if that is not true, it would be helpful if you would share that with me.

Dr. MASON. We are placing those people wherever they want to be placed, but the workload will be carried from our Cincinnati offices.

Mr. EDGAR. There is a great deal of concern in the Philadelphia area, with the heightened interest and community right to know and workers right to know what chemicals they are being exposed to, to see the reduction of the very office that gave information and have been helpful in identifying safety and health-related issues at the worksite.

That's another issue for another hearing, but I was interested in your comments about budgets and needed to ask that question.

Let me ask you just a couple other questions relating to your testimony. Can you describe for me in a little bit more detail the hurdle that has caused the stopping of the exposure study based on inability to track veterans who were exposed versus veterans that were not exposed? Is it my understanding that you are taking the records of the Defense Department as to where the flights took place, and taking the veterans who were in those military areas of operation and trying to correlate direct exposure and those veterans?

Dr. MASON. That's basically correct. And we appreciate Dick Christian and his staff for the fine work that they're doing. They take the military records of the Ranch Hand spraying, the fixed aircraft spraying, and then there are almost no records of spraying that was done on the ground in the perimeter areas, but trying to correlate spraying patterns as we know them with the placement of individuals within the military units. Those records were never established for the purpose of doing epidemiological studies.

When CDC got into this, it was assumed there would be records that could determine exactly where an individual was on a given day, and that could be correlated with known insecticide use. I think with the finest use of existing records, you cannot separate between exposed and unexposed. You can get some hope approximations, but it would be a dis-service to veterans and to everyone to proceed with an expensive study of this nature if you can't clearly differentiate between who's been exposed and who's not exposed. Without that, you have no basis to proceed with doing a study.

That is the difficulty. It isn't politics. We have never had any concerns expressed to us as to whether the study should go ahead other than based upon the science of that separation.

Mr. EDGAR. Is it my understanding that the methodology that you used gives a 2 kilometer swathe on either side in the area where the plane traveled, and it is only under that 2 kilometer path that you were in search of veterans who were exposed?

Dr. MASON. Here's where we have used the best experts in the military, at CDC, and wherever we could get them, to try to determine how you do determine those exposure limits, how far can you go. Is it 2 kilometers, is it 5 kilometers? At best, these are the best guestimates of the experts.

Dr. Houk, is there anything you would like to say specifically on that?

Dr. HOUK. In addition, it has been demonstrated in record reviews that the Army policy of not exposing troops to aerial spraying within 30 days was very effective. There are very few troops in that category.

With Dick Christian's group itself, we are looking not only at that but any evidence for spraying around the base camps, evidence for the aborted mission, any kind of spraying that is available from those records. In addition to the acute exposure, we're looking at the long-term exposure. Someone may have been in an area that was sprayed several weeks ago or several months ago, that there is still some residual stuff there. All of these things are brought in to the exposure index.

Mr. EDGAR. How about the accuracy of the pilots?

Dr. HOUK. The accuracy of the Herbs tapes is fairly well accepted by everybody to be relatively without question——

Mr. EDGAR. Including the pilots?

Dr. HOUK. That has been looked at by the National Academy of Science. It is said by some that the pilots, some pilots, did not accurately depict their locations. I will let Mr. Christian specifically address that.

We have had a lot of talk with the Academy of Science, with the pilots, with the Air Force, with Ranch Hand, and the general consensus is that the information on the Herbs tapes is accurate.

Mr. EDGAR. I hope those pilots fly better than those who spray for mosquitoes in Pennsylvania and New Jersey, because if you've ever been to a picnic when they have come over spraying, you realize that sometimes the pilots are off.

Dr. MASON. That's part of the problem, that we recognize. But we have had to assume that at least these were relatively accurate. That hasn't been the problem. That is probably some of the best data we have, even with all of its deficiencies.

Mr. EDGAR. What I hear you saying is that you have now determined that that methodology doesn't work very well, it's inaccurate, and it's not going to give us the answer that we want; but you have now invented a new methodology, you hope, that you will have some determination by September, using blood samples and fatty tissue samples, to see if the exposure can be measured by blood and fatty tissue, is that correct?

Dr. MASON. That's correct.

In 1983, this was considered—is there a way to get a piece of the veteran and test him for herbicide or dioxin. But at that time our technology was such that it took a thumb-sized hunk of fat, and the accuracy of the determinations was not good. We're talking about parts per trillion, if you can imagine numbers of those kinds. Also, there was little information in 1983 about the half-life of dioxin in the human body. It was thought to be around a year, and with a year's half-life in the 15- to 20-year period that's passed, by half-life, you've got 20 half-lifes and you would have no dioxin left.

But since that time, we know that the half-life is longer than 5 years, and probably as long as 10, and we have been able to increase the accuracy of these measurements. It now looks like blood, 200 ccs, or perhaps we can get down to even 100 ccs of blood as a surrogate for fat. That is what Dr. Houk is currently testing, to see whether a blood sample from the veteran can determine his body burden of dioxin, and then relate that to exposure in Vietnam, to see does that veteran have a normal background that all of us—You and I all have dioxin in our fat. But are those veterans, from the best military records we can put together, do they have more dioxin in their blood than those that appear not to be exposed by military records.

If these tests show there is no difference, then we have nothing to do on. If the tests show differences, then we can go back and we will have at least a clue as to how to get an exposed and nonexposed cohort.

Mr. EDGAR. Your testimony suggested a two-step procedure, and that is, first explore the new verification measure of blood and fatty tissue, and secondly, a test of military records.

How long will this whole process take until a new Agent Orange protocol can be written?

Dr. MASON. Dr. Houk will have completed the blood-fat comparison by the first of September. Then a protocol would need to be developed. The protocol would involve approximately 400 veterans, 150 that the military records suggest were not exposed, and 250 that fall into various exposure categories. The protocol would spell out how those two groups, with a total of 400 veterans, would be tested to see if we can get differences. It would take up to 4 months, the first of the year, to develop that protocol, and another 4 months after we had approval to actually do those samples on the 400.

Mr. EDGAR. And another how long until the report is delivered to Congress and we sign off on this process that began in 1979?

Dr. MASON. The final, or just getting through that process, as to whether we've got the data to move ahead?

Mr. EDGAR. Let's suppose that what you determine in September is yes, you can go parts per trillion, and you go through that process. When can we, as Members of Congress, those of us who are left at that point, get access to that study?

Dr. MASON. I'm going to ask Dr. Houk, but please don't overpromise.

Dr. HOUK. As Dr. Mason said, by the end of August we will have the relationship between the fat and the blood worked out and peer-reviewed. A protocol would be put together as to how to select those 400 individuals. Those 400 individuals will then be looked at

and all the different methods of establishing exposure through military records, through their own questionnaires, et cetera, to see if there is a best way or several ways to see if exposure can be done through military records.

It is our estimate that, from the time we begin that process, that we can have significant initial data for review within approximately 4 months. That would take an additional period of a couple of months after that time to ensure it was the best science to have it peer reviewed and then transmitted to the Agent Orange Working Group.

Dr. MASON. Now, what about the final study?

Dr. HOUK. If the validation study shows that it is possible to use military records or a combination of things to clearly identify exposed from unexposed individuals, then the protocol for that study, how we do that, can be done. The protocol basically is what we do is already done. We're just waiting for how we would select the individuals.

If that go ahead is given to do the overall study, it would take approximately 18 months from the beginning of that to completion.

Mr. EDGAR. That's 2 years, right, from today.

You have said you need 400 veterans for the study. How many exposed veterans were found by the subpanel and ESG?

Dr. MASON. I'm going to ask Dr. Keller, who has been the chairman of the science panel, to answer that question.

Mr. EDGAR. I ask that you do it in 10 seconds, or save your answer.

Why don't we save the answer until after this vote.

Dr. KELLER. I'll have to look some material up.

Mr. EDGAR. Thank you.

And a follow-up question is, are there enough. You spent some time looking for veterans who were exposed. Do we have enough of a group to find that 400?

Dr. KELLER. That's questionable, and that is part of the development of the protocol for the verification study that needs to be done.

Mr. EDGAR. The committee stands in recess for 12 minutes.

[Whereupon, the subcommittee was in recess.]

Mr. EDGAR. The subcommittee will resume its sitting.

I just have one question to ask—and we have a number of questions we're going to ask for the record and ask that you respond to. There may be another question or two after my colleague, Mr. Ridge, asks some questions, and my colleague, Mr. Daschle.

There are private citizens who have handled the chemicals, that we affectionately use the code word "Agent Orange" for, for many years. We used that same chemical or chemicals like that in civilian use. It occurs to me, having listened to some of the testimony over the years, that some of the parts of the chemicals used were labeled in this committee as the most dangerous known chemicals available, the ones that impacted on the body in the most negative way, and there were some very graphic descriptions.

Some of the chemical companies in the sixties and early seventies went to great lengths to make sure that some of their knowledge of the impact of these chemicals on the human body was not forthcoming quickly, and many private sector individuals claimed,

and in some instances won some legal battles, that their exposure to these chemicals, in the production of the chemicals and in the use of the chemicals, caused them some difficulties.

Now, I may be overstating it, and correct me if I am. But it seems to me that we're using a chemical that in the private sector we had determined as being very dangerous. It then was used in the public sector in a public war that we watched. I wondered if any of you who have been involved in this process of looking at these studies have analyzed the data from the private sector. Do you intend to go and do some blood sampling of any people on the civilian side who handled these chemicals, to give us some data as to whether or not exposure in Vietnam versus exposure in the private sector had any impact?

Dr. MASON. Some of the work to validate the fat-blood relationship is—in fact, most of that is being done by looking at people who have either been occupationally exposed or recreationally exposed in the United States. So this work is being done on nonmilitary populations and is really not part of our Agent Orange work. It is to carry out our work with regard to occupational health and safety.

Let me ask Dr. Houk to address that specifically.

Dr. HOUK. Yes. One of the difficulties of any chemical, Mr. Chairman, is to determine whether an individual has been exposed or not. One cannot use historical records very often unless there is a method to validate those.

We are developing the technology and leading in that development as Dr. Mason said, for the purpose of doing this. We know that in dioxin exposure in Missouri, the people who lived on soil that was contaminated with dioxin, some of those have higher levels of dioxin in their fat than background levels in this country. We are now working intently, trying to measure the blood of these people so that we can do a validation.

Also, one of the difficulties with dioxin in the literature, it became very fashionable in 1978 that every time one used the word "dioxin" it was always followed by "the most toxic chemical known to man." The human data on the toxicity of dioxin is based upon acute toxicity in an animal setting.

In industrial exposures, chloracne has been demonstrated but other things have not. The population groups, however, are sufficiently small that one does not have a great deal of confidence in that. NIOSH has proposed studying production workers in this country, and we will do the blood levels in those to get the ascertainment of fat.

We studied a population that lived on dioxin in Quail Run, MO, and the only thing out of that study came some abnormalities of the people's immune system. We don't know whether that's an adverse health effect or not at this moment and are setting out to demonstrate it. That is, however, a rather disquieting finding.

We know the dioxin literature well. A member of my staff, whose name many of you will recognize, Dr. Renatta Kimbro is the world's authority, one of the leading world's authority on this compound. We are addressing all of these issues to the best of our ability. This is the reason that we proposed being able to do a blood

study for validation of the exposure, to see if we could separate the exposed from nonexposed veterans.

Mr. EDGAR. I don't want to pursue this, but it seems to me that you have some data, because you have exposed and unexposed in the private sector, and that universe of people seems clearer than what you're telling me about the ability to find that in Vietnam. It would seem to me, if you want to validate whether or not your test works, one clear way to do it would be to test the blood and the fatty tissue samples of those who worked with the chemicals and those who didn't live near the community or didn't live in the area, to make that correlation. If that correlation can be made, then it seems to me it is reasonable that you might be able to test 400 or so veterans, some in the area and some out of the area, and get some correlation.

Dr. MASON. And that's exactly what we're doing. The test and the validation, the study that will be completed by September, is indeed a study of occupationally-exposed people in the United States. That is what will be finished up by then.

Mr. EDGAR. I yield to my colleague, Mr. Ridge.

Mr. RIDGE. Thank you, Mr. Chairman. And thank you, gentlemen, for your testimony.

I am pleased to note that two of the three studies that you initiated are moving along, progressing nicely, and on target. I am also pleased to hear that, from your view, it hasn't been a question of budget restraints that have derailed the Vietnam exposure study. But I would share with you a thought that I think is shared with my colleague, the chairman of this committee, and Members of Congress.

During the Vietnam war, not conflict, but during the war, we spent about $300 billion and sent about 3 million men and women over. If it ever came to a question of money as being responsible for derailing or postponing or preventing the proper conduct of testing, we would like to know about it immediately. If we spend $300 billion during the effort, the modest amounts that you need to complete that study certainly would be available through Congress under any circumstances, regardless of Gramm-Rudman or whatever the next version of that effort may be called at some future date. So I think you should leave here knowing that, and I think it is a view shared with my colleague, the chairman of the subcommittee.

I do have some questions about methodology, and perhaps they should be directed to other witnesses, but I would like to get your input as well.

The civilian population to which you have referred, I sense you feel, at least at this point, is statistically there aren't enough people out there that have been exposed to give you a broad enough sample to reach independent conclusions?

Dr. MASON. Independent conclusions on the relationship between dioxin and disease?

Mr. RIDGE. Correct.

Dr. MASON. There are studies that have been done in Italy and Sweden and in the United States that have looked very, very carefully at the relationship between dioxin and disease. Chloracne, which is an acute problem, where they get a cutaneous manifesta-

tion, is seen after acute exposure to high levels of dioxin. It is the long-term effects that are being looked for, and there are suggestions from the Swedish literature and other literature that there may be certain soft tissue sarcomas, tumors, that result very infrequently.

That is one of our three studies. Even with the cohorts that we're following with the Vietnam experience, since these sarcomas occur so infrequently, we wouldn't expect to pick up differences between exposed or nonexposed based on a sample of 6,000 or 7,000 people. So we go to tumor registries throughout the United States and look for those sarcomas, and then come forward from the sarcoma to see if that leads back to Vietnam veterans. That study won't be completed until 1989 because the tumor registries will not have reported enough of those kind of tumors to make the study valid.

So the problem is, the occupational exposure, particularly in the United States, as well as in other countries, involves small numbers of people, and so no clear cut association between dioxin and these tumors has been established. But one can't say there isn't an association because of the small numbers involved. That's why there isn't a lot of data to relate dioxin to human disease. But because of animal studies and studies using smaller groups, there is a suggestion. That's why you need larger populations or longer periods of observation, and that is going on in civilian populations at the present time.

Mr. RIDGE. With regard to finding an appropriate number of Vietnam veterans who may or may not have been exposed, I guess I am not incredulous because I understand the precision with which you work and you want to work in the scientific community, and the need to establish a direct medical link and scientific link between exposure to dioxin and any resulting physical consequences.

But when you have data that indicates that the service policy not to expose ground troops to areas that had been sprayed within 30 days, and you can conclude that that policy was rigorously observed, and that, in fact, few if any troops were exposed within 30 days, it leads me to conclude two things: unless you're saying that no troops were exposed as a result of your study, then you're limited; but I didn't get a sense that you found there weren't some troops exposed. And secondly, have you identified those men—and perhaps some women—but men or women who may have been exposed to areas that had been sprayed within 30 days or prior to the conclusion of 30 days? Have you identified troops or troop movements within those areas?

Dr. MASON. What we have found is that the military, according to the records, were very careful to abide by rules that, after spraying, they would be kept out of the area and they wouldn't spray where troops were involved. There is no question that some troops were exposed. Even if you asked them, though, you can't go on that—You know, you could say "Were you exposed?" They can't always distinguish between spraying against mosquitoes and other things that went on. So by questioning people, you can't use that as an exposure history.

But there is no question that some were exposed to Agent Orange. The problem gets back to one of dose, as to whether it was

a very low dose or whether they were repeatedly exposed. That is where the difficulties are. Most of the people were not exposed who fought in Vietnam, and it is like trying to find a needle in a haystack—who was significantly exposed—so we can compare them with an unexposed group.

Mr. RIDGE. How do you define significantly exposed? What level of exposure do you require to be scientifically established and perhaps corroborated through military records before that particular veteran is considered to be one to have been exposed to a sufficient level of the chemical to be included as part of your sample group?

Dr. MASON. Dr. Houk, do you want to describe some of the classifications?

Dr. HOUK. Yes. One of the things we're looking at is both the acute and the chronic exposure, Mr. Ridge. To have biologically meaningful things, we originally were looking for within 2 kilometers, within 2 days of the spray mission. Then the idea that was developed by Mr. Christian and his folks about the perimeter sprayings and the other sprayings which may be the most important part of exposure in Vietnam, rather than the aerial spraying, which apparently was relatively well handled and keeping people out acutely.

We finally had—This has been one of the major questions and a major difficult question that we have had. It finally has come down to looking for at least 14 days, of the man's service in Vietnam for the full year, should have been within 2 kilometers, within 2 days of one of the kind of spraying missions, and then some other things taken out of that.

The hope is, however, if the validation thing of the blood works out, then we will have direct evidence of the person having these sorts of exposure on record who can fall into levels, say, two times higher than background, three times higher than background, four times—whatever that turns out to be. Then there will be some hard, scientific information upon which you can base the exposure recommendation if it is possible to separate them.

I would like to point out, because it was a question of the committee, either you or the chairman used the word "men or women". The Agent Orange studies were designed specifically for men. We opted early out, as we told this committee, not to include women. Because of the way the study was designed, there would be so few women included in that that it would have no chance of having any relationship showing whether there was a positive effect or not.

Mr. RIDGE. I appreciate that last comment. I think I referred to the men and women who served, and often we forget there were literally thousands of women who served in that effort as well. If for reasons of identification you have confirmed that there was not a sufficient group, I suspect that the blood test confirmation would be as valid to them in future years as well. I don't know. But I appreciate that comment.

Mr. Chairman, I have several other questions, as you can well imagine. I don't want to monopolize this hearing, so I would ask unanimous consent I be allowed to submit them in writing and that they be included as part of the record.

Mr. DASCHLE (presiding). I commend you, Mr. Ridge, for some excellent questions. I wouldn't want to deny the opportunity to you to ask them orally. After we have asked Mr. Smith and Mr. Rowland and others, you are welcome to proceed in addition, if you wish. I think you have enlightened the entire committee with many of the questions you have asked and they have been very helpful.

I might follow up, in fact, on the last one you asked. You were asking about the frequency of exposure, and I think Dr. Houk mentioned 14 days. I would be interested in knowing what criteria one uses to arrive at 14 days. What is it about 14 days that makes that significant?

Dr. HOUK. It was evolved, Mr. Daschle, on the basis of our looking at the records. As everybody remembers, early on we thought everybody was exposed and we had difficulty finding people of sufficient exposure. The science panel looked at this and several other groups looked at this and that was thought to be the least amount that would be biologically plausible to have caused any harm. Again, as we proceed with the validation study and the other, that will be addressed and looked at.

Also, it is based, in part, on work that we have done in the civilian population in Missouri and elsewhere, people who lived on dioxin-containing soil, people who worked in dioxin-related industries, and in Missouri, the people who rode horses on the horse arenas that were sprayed with the oil containing dioxin. These groups have substantially higher levels of dioxin than the background levels that we see in the general population, as much as five, six or seven times.

Mr. DASCHLE. But it sounds like you're saying, Dr. Houk—and you can confirm this or clarify it for me—that it is sort of a concerted guess. You have the consensus among those experts who have looked at the available data, and it is nothing more than a guess, would you not say?

Dr. MASON. Just a comment before he answers.

At CDC we are very aware of the problem as to what constitutes exposure, and that is why, as I mentioned in my testimony earlier, that as we have tried to work our way through this, CDC did submit to the Agent Orange Working Group and to OTA a protocol that would consider treating exposure as a continuous variable. In other words, you would try to start with zero exposure and maximal exposure and look at a range of responses between zero and what might constitute the most serious exposure that could occur, just because of the difficulty that you're talking about—how do you define exposure.

But this protocol was rejected because at least some felt that that was not a good comparison base. I just throw that out to show you how difficult this really is. We have turned over every stone we can find to try to get a group that can be scientifically studied.

Mr. DASCHLE. Wasn't that rejected by the working group and OTA as conceptually deficient?

Dr. MASON. Yes.

Mr. DASCHLE. It was.

Dr. MASON. Yes, that you have to define something that you regard as constituting significant exposure. So somewhere along the line it is an arbitrary decision. You're absolutely right.

Dr. HOUK. Fifteen days is an absolute guess. It is the best that we can do, as anything less than that would have no biological plausibility of having produced any adverse health effect, whatever those are that we don't know. It is an absolute guess, to be sure.

When we began this and as it has evolved over time, it was the consensus that the ground troops would have had significantly more exposure than 14 days. When we recognized the difficulties of finding enough people heavily exposed to have two clear-cut cohorts—one heavily exposed and the other one nonexposed—we consulted with the best minds in this country that we could think of and that's the reason we came up with, as Dr. Mason mentioned, with using exposure as a continuous variable. Then you could handle that statistically somewhat better and differently than you could do that.

As Dr. Mason mentioned, and let me reiterate, we take seriously the mandate of doing the study, if it is scientifically possible to do one, and we have looked at every option that we can look at of trying to address that particular issue, the issue of exposure.

If we can find the men—I point out that in that Vietnam Experience Study, we were able to identify 92 percent of the names provided to us by the Army, with addresses from 1968 and 1969. Of the ones that we were able to identify, and those that were contacted, 92 percent of the veterans agreed to participate in the interview process. Again, that is their interest and the interest of the service organizations, in encouraging them to participate, to get this. If we can find the men and can separate men into exposed and nonexposed, it is possible to do the study and we will be able to identify those individuals. If the Vietnam experience holds, and we think that it will, they will participate.

The problem is determining whether you can find a sufficient number of people who have been exposed and a like cohort who have likely not been exposed to do a scientifically valid study. We probably could find individuals who, because of special occupations, had the most likely exposure, such as the Chemical Corps, et cetera. But that would not relate to the overall issue.

The Ranch Hand Study is already going on, and that relates to the people who, by convention or thought or guess, if you will, in our judgment have the most likelihood of being exposed to these agents.

Mr. DASCHLE. There are so many different angles from which to approach our questions this morning, and I am already feeling the frustration that I know that Mr. Ridge felt because my time has already run out. I could pursue this for another 15 minutes.

But before I relinquish the questioning, the impression I have, from what little I have heard and from the information provided me in preparation for the hearing, is that the questions being asked and the information being given, with some exceptions, could have been given in 1980, 1982, or 1984. There is a tremendous amount of frustration with regard to the extreme delay with which we are moving on this whole issue. There is a delay that is understandable, given the complexity, and there is a delay that would not be understandable based on some recalcitrance within the scientific community, within CDC or within the Environmental Health Center, indicated in part by a reluctance, for example, not

to give us the science panel's report when it was specifically asked for.

Could you address that, Dr. Mason? Why was it not provided to the committee after it was specifically requested?

Dr. MASON. My understanding is that, as a report of the Domestic Policy Council, before Under Secretary Newman could release the report, he had to have the permission of that Council. That permission has been requested and as soon as they rule on that, if it's affirmative, we would be happy to provide that.

Mr. DASCHLE. And how long will that be?

Dr. MASON. I have no way of answering that question.

Mr. DASCHLE. Then we're right back to where we started, aren't we?

Dr. MASON. The difficulty—I just want to say that it would be easier to just say Vietnam is not the place to do an Agent Orange exposure study. I think that's the problem that you come back to again and again. There are these other ramifications, but no one wants to commit money for something that isn't scientifically sound. Because of the desire on the part of the veterans and Congress, CDC and ESG are pulling hair trying to put together a scientifically feasible study. We're going to do our best, if that's what people want. But at some point someone is going to have to say "This study should not be done."

The last try, the "last hurrah", as far as I'm concerned, is the validation that we have talked about. If there is no go on that—you can ascribe this to all sorts of political or monetary things, but the problem is simply there is no science there. We would like to——

Mr. DASCHLE. Are you saying, Dr. Mason—Excuse me for interrupting, but you said something a moment ago that I think certainly needs clarification.

Are you saying that this study should not be done, or cannot be done?

Dr. MASON. Unless we get something from what we have talked about in validation, it cannot be done. It should not be done because it cannot be done validly. And the problem, the delays, are simply that scientists that aren't willing to do something that isn't scientifically sound haven't yet found a way to produce the results, whether the results are there's an association with disease or there is no association to disease. We do not want the results to be something that came up by chance rather than there is a cause and effect.

Mr. DASCHLE. That's interesting. Dr. Houk, in 1982, said all we have to do to get a protocol is lock these guys up for 2 weeks in a room and we would have it.

Dr. MASON. And we had the protocol within 2 weeks. That's the point we're making. But the protocol said we will use these records that we have been told exist, that will give us this data about exposure. And those records don't exist. They were thought to exist. So he got the protocol as fast as he said he would, but the protcol included how records would be used. It was assumed—you thought, we thought, everyone thought—that most of the people had clearly been exposed, and how in the world do you find people that weren't exposed? And here we found, when the records were opened, that that kind of data wasn't there at all.

First of all, very few were exposed, and you can't even, with certainty, identify who they are. So the protocol was produced. Our track record is good. I'm proud of it. It isn't because someone has done their job; it is because the records are not adequate to be used as a basis for a scientific study, pure and simple. That's the delay.

Mr. DASCHLE. If you can't identify these people, how do you know whether they were exposed?

Dr. MASON. We don't. And that's the problem.

Mr. DASCHLE. But now you're telling us that you're going to have a blood marker study that could be completed as early as September, 4 weeks from now——

Dr. MASON (continuing). Which may be able to shed some light on differentiating between exposed and nonexposed. If it will, then there's another glimmer of hope that a scientifically sound study can be carried out. If the answer to the blood study is negative, then we have no other place to go. It isn't because of lack of interest, lack of priority, lack of money. It's lack of data upon which to base a scientifically sound study.

Mr. DASCHLE. Well, I would like to pursue this for a lot longer period of time, but I know that I'm already taking up time that is rightfully the time for Mr. Smith and Mr. Rowland and Miss Kaptur.

Mr. EDGAR. Mr. Chairman.

Mr. DASCHLE. Yes, Mr. Edgar.

Mr. EDGAR. Mr. Chairman, I would like to officially place you in that role as Chair this morning. I have to leave for a few minutes for another important meeting.

I just want to say to Dr. Mason before I leave that there will be some testimony from the Office of Technology Assessment that is slightly different than your analysis of what can and cannot be done. We're all as anxious as you are to know what we should, in fact, expect from this study.

I hope you can understand our frustration. In 4 weeks, we want to hear clearly from you whether or not this new approach not just sheds light and sheds blood on this study, but whether or not it is worth pursuing beyond September. I mean, we need to know whether or not we should tell our Vietnam veterans "Hold on for another 2 years; we're coming and we're trying to put it together", or whether or not your earlier comment, that you're not sure whether it can be done at all, is in fact more realistic. Because I don't think it is fair at this point to drag this thing out again and again and again and hope or wait for some more advanced studies so that we can get parts per "quad-" trillion or whatever the next thing is beyond trillion. It just seems to me that we need to know some answers now so that we can tell people what to expect in the study.

Also, I think my colleagues and I are going to have to determine whether or not, if you're right, that we can't do it scientifically, whether or not we presume causality, as we have done in an earlier piece of legislation, is an appropriate thing for us to do.

But I want to commend my colleague, Mr. Daschle, who has been a leader on this issue and thank him for chairing the next hour.

Mr. DASCHLE. Thank you, Mr. Edgar.

I have a statement that I had intended to make had I been here on time. I would like at this point to ask unanimous consent to have the statement inserted in the record and call on Mr. Smith.

[The statement of Hon. Tom Daschle appears on p. 85.]

Mr. SMITH OF NEW JERSEY. I thank the Chair for yielding.

First of all, I want to commend the acting chairman for his advocacy over the years on behalf of Agent Orange victims. As the original sponsor of H.R. 1961, and throughout my tenture in Congress, he has always been outspoken on this issue and both he and I during markup tried to amend that legislation to expand it to include other potential hazards that are associated with Agent Orange exposure. I want to again commend him for that.

Some of our colleagues earlier today indicated in their testimony that the administration was in some way causing this study to go afoul. Dr. Mason, I was wondering if you could tell this committee whether or not there has been any interference by the administration, any attempt to retard the progress on this important study.

Dr. MASON. There have been no attempts to retard the progress.

Mr. SMITH OF NEW JERSEY. They have been supportive?

Dr. MASON. They've been supportive.

Mr. SMITH OF NEW JERSEY. I thank you for that, and I hope the record clearly shows that.

Could you tell this committee, in addition to Agent Orange exposure and it's impact on our servicemen, will the study enable researchers to discover any other kind of common thread of exposure to any other carcinogenic material in Southeast Asia and how would that be dealt with? For instance, say Agent Blue had some substance in it, or some other common phenomena in Vietnam that could have caused some of the problems we're seeing associated with our men.

Dr. MASON. The Vietnam Experience Study, which is one of the three, and one that is going along very, very well, compares a group of Vietnam veterans with veterans matched in every way except they served outside of Vietnam. That study is going along magnificently. It is on schedule. It should be able to determine whether mosquito exposure or some viral disease or marijuana exposure or whatever happened in Vietnam, even if collectively Agent Orange had some underlying problem among Vietnam veterans, then we would expect to see more physical illness, mental illness, laboratory abnormalities in the Vietnam cohort as compared to the non-Vietnam cohort. So that study would get at those kind of problems.

Mr. SMITH OF NEW JERSEY. When can we expect the results on that one?

Dr. MASON. Dr. Houk.

Dr. HOUK. The first part of that, the mortality study, is now in peer review. It will be published this fall. The questionnaires have been completed. The medical examination will be completed by Lovelace Clinic at the end of September. Then those data will be put together. It was decided not to publish those two reports separately, but it made more sense and made more meaningful data to put the study in. We anticipate that will be peer reviewed and published in the middle of 1987. That will complete the Vietnam Experience Study.

I would like to point out that even if it is not possible to do an Agent Orange exposure study on the people in Vietnam, we have on each of the individuals who participated in the Vietnam Experience Study a certain amount of blood frozen and stored. It would be possible to go back and look at the dioxin issue if there were any findings that would suggest that that needed to be done.

I would point out I think the blood test—not to over-promise—has the potential of being able to answer scientifically some very difficult questions that you gentlemen have been faced with for the last several years in this regard.

Mr. SMITH OF NEW JERSEY. I thank you for those answers.

Mr. Chairman, unfortunately, I have a markup in Foreign Affairs that has been underway for over an hour, so I am going to have to leave for that. But I will take the material and I thank you again for your leadership.

Mr. DASCHLE. I thank the gentleman from New Jersey for excellent questions.

Miss Kaptur, do you have any questions?

Ms. KAPTUR. Yes, Mr. Chairman. I wanted to ask a question specifically regarding the women veterans. I know that we have been discussing some of the complexities of the identification of combat companies' locations and so forth and your difficulty in determining where they were and, therefore, whether people were exposed and how they were exposed. We have had a great interest in seeing women veterans incorporated in this study.

I am wondering if you could address the timetable for that and, in view of the difficulties you're having with the men's part of it, how women fit into the Agent Orange part of the study as opposed to the Vietnam experience only.

Dr. MASON. The Veterans' Administration is currently working on a women veterans experience type of study. It is like our Vietnam experience which involves male veterans. They are carrying that out and I understand their in the request for proposal stage of getting contracts to do that study.

That would not zero in specifically on Agent Orange exposure would be Vietnam experience of women in Vietnam versus matched women not in Vietnam.

Dr. HOUK. Miss Kaptur, it is not possible from records to do an Agent Orange exposure of women veterans. One could do the Vietnam experience. We have identified with the Army and the VA significant numbers of women who served in Vietnam and who did not.

The other issue that is always addressed is then how about the nonveteran female, the Red Cross worker, et cetera, who served in that era of the war. It is not possible even to do an experience study of those people since no central record exists of all of the women who served in those areas. And you cannot do a study by asking for volunteers. It would not be valid.

Ms. KAPTUR. As I remember from my college experience in research, you can go to central records keeping, which in this case sounds very weak and not terribly useful, or one can work from the bottom up with anecdotal evidence and to try to build a case from empirical data.

I guess one of my questions for both women and men would be, have you attempted to work through the VVA and some of the other organizations which have members who do have this kind of anecdotal evidence? I had one man come up to me in my district at a VVA meeting who had soft tissue sarcoma and he says, "Marcy, we don't understand what the big problem is in Washington, why they can't do these studies." He said, "I sat in that stuff. I was mixing it with paddles. I know where I was." Now, maybe the Army doesn't know where he had been and maybe their records are bad, but he sure knows where he was. He has been undergoing treatment ever since and is very close to death.

If the excuse is the records are bad, can't you work the other way, both with men and with women? What has been your experience in working through the veterans' organizations to identify a pool of people?

Dr. HOUK. We are working the other way on the special cancer studies, using the cancer registries of this country, because of the numbers of people. It is not possible to do a study simply by asking for volunteers. To have a scientifically valid study, one has to have the universe of the population that served, and then select from those on a random basis the people that you are going to study. For example, that is how the Vietnam Experience Study was done, to try to find a random sample of 17,000 people taken from a particular timeframe in Vietnam.

We can identify the women who served in Vietnam from the locations, and Mr. Christian can provide the units that were likely to have females in them. There are about 7,000 females who served in Vietnam and it is possible to get a cohort of about 13,000 who did not serve. One of the ways that we found in identifying the women—since the military records don't exist, male and female, until you go to each individual record—was to have a paperback book with 2,500 names mostly commonly assigned to baby girls and, using that system, you could identify a very large number.

We found a few men whose first name was Ruth, but that's a good system of identifying—about 85 percent of the people could be identified using that system.

Ms. KAPTUR. But in the Vietnam Experience Study, then, the factor of Agent Orange wouldn't fall out of that, would it, if you're not looking for it?

Dr. HOUK. If there becomes the possibility of doing a blood test later on the women, that could be done because the blood is equally applicable to women as to the men. The science panel and the Agent Orange Working Group has looked at this question intensely for about the last 3 or 4 years and have concluded that, on the basis of records, it is not possible to do an Agent Orange study. It would be possible to do a Vietnam Experience Study, and I believe the Veterans' Administration already has an RFP requesting that that be done,

But again, you cannot do a valid study unless you have the whole denominator. We opted, as is specified in the protocol that was written in 1983, we made a very conscious decision not to include women in the Agent Orange study and the Vietnam Experience Study that we were doing because the selection of the participants would have allowed for the inclusion of so few women that

you would have had no valid results and it simply would have been tokenism to include them.

If a study of women's issues needs to be done, the study should be done specifically addressing those issues.

Ms. KAPTUR. Mr. Chairman, I know I'm over time, but I just want to know, for instance, if I have veterans in my district that claim that they mixed that stuff in barrels, and if I were to give you their names, you would say they weren't randomly selected and, therefore, they're not worthy of being incorporated in the study? Do I understand you correctly?

Dr. HOUK. Yes.

Dr. MASON. It isn't a matter of worthiness in that sense. Those that actually were involved in mixing, at least large cohorts are being handled by the Ranch Hand studies, where the Department of Defense is looking at a group of veterans who actually mixed, worked, sprayed and are undoubtedly at higher risk than anyone who was just exposed as a result of spraying. So that is a special study in itself to take a look at those individuals.

Ms. KAPTUR. At those people?

Dr. MASON. Yes. Because there is no question that occupational exposure—and that would be a type of occupational exposure, actually working with it and spraying with it—would put them at higher risk than the veteran in general. That study is ongoing.

Ms. KAPTUR. Thank you, Mr. Chairman.

Mr. DASCHLE. Thank you, Miss Kaptur.

Mr. Rowland.

Mr. ROWLAND OF CONNECTICUT. Thank you, Mr. Chairman. I would just like to ask a few follow-up questions, if I may.

In your answer, Dr. Mason, to one of the questions posed earlier, you made reference to getting approval from the Council before releasing the study. Is that the same study you're referring to that may be released, you think, in September, or you're unsure of when it could be released? I was a little bit confused.

Dr. MASON. On the science panel, the exposure assessment subpanel, that was the group chaired by Mr. Al Young that reported to Dr. Keller, we have requested permission from the Domestic Policy Council to provide that to this group.

Mr. ROWLAND OF CONNECTICUT. When was that request made, approximately?

Dr. MASON. I think we got the request for that study 1 or 2 days ago, on Thursday, and the request was done the same day.

Is that right, Ed, that the request is dated July 30 and the request from Robert L. Racklin to Dr. Ralph Bledso of the Domestic Policy Council was dated July 30?

Mr. WEISS. That's right.

Mr. ROWLAND OF CONNECTICUT. Thank you.

One of the other issues that came up, especially from our colleagues earlier today, was the budget restraints, and I'm glad we put that to bed. The other was with regard to priorities.

Just for my own information, and I think for those on the committee, approximately how many studies do you do in a year? Obviously, some are pending from year to year, I would imagine. But a ballpark number, how many studies does the CDC do in a year?

Dr. MASON. Well, few of them are of the magnitude that we're talking about here, of large cohorts, sophisticated examinations of large groups of people, in terms of small studies, health hazard evaluations and things of that nature, literally hundreds of year. This one is specifically mandated by Congress and we don't put Agent Orange even in our priority schedule. That is going to be carried out, regardless of what else comes up.

Mr. ROWLAND OF CONNECTICUT. Is it of such high priority that it is beyond the priority schedules; is that what you're saying?

Dr. MASON. That's what I'm saying. It's beyond the priority schedule.

A statement was made on the use or misuse of funds earlier. I want all of you ladies and gentlemen to know that, if anything, CDC is subsidizing Agent Orange studies. None of my salary is taken out of that Agent Orange money, Dr. Houk's isn't, and CDC is subsidizing this. In no way is a penny of that being diverted to non-Agent Orange types of responsibility.

Mr. ROWLAND OF CONNECTICUT. Would it then be accurate to say that the Agent Orange study is of the highest priority within CDC?

Dr. MASON. Absolutely the highest priority. It isn't lack of priority that leads us to this point. It's difficulties with the science.

Mr. ROWLAND OF CONNECTICUT. Thank you.

Dr. Houk, did you want to make a follow-up comment?

Dr. HOUK. Yes. The Agent Orange studies are done out of my center under Dr. Mason, a separate budget and separate staff. The studies will proceed. Nothing in CEH's activities interfere or influence the Agent Orange study.

The idea of the blood test and the fat test, to give you an example, comes separately from the work we are doing that is being used in Agent Orange. To give you some order of magnitude of the cost of what we estimate we have done that far—which is not billed to Agent Orange and is not done as part of the study but trying to devise this technique—is between $1 and $2 million over the last couple of years. That will be able to be used we think to make a recommendation to the Agent Orange Working Group and ultimately to the committee of whether or not it is possible to do a scientifically valid Agent Orange exposure study.

We are as interested as you are in getting that addressed and answered, whether or not it can be done. If it can be done, we will do the best scientifically credible study that we can. If it cannot be done, we will say that it is not possible scientifically to do this.

If you read the 1983 protocol that was developed, that statement is boldly set. We sequence the Vietnam experience and the Agent Orange study, knowing that we would have difficulty working out the exposure assessments, and gave an additional year-and-a-half to do that. We stated explicitly that these procedures would need to be tested. We also stated explicitly in that document, and many times in letters, that if it is not possible to do a scientifically valid study, we will say so and will not participate in doing one that is not valid.

Mr. ROWLAND OF CONNECTICUT. Thank you, Doctor.

A closing question. Is it correct to say that the Agent Orange study is unaffected by resources and/or other projects or other priorities that you might have at CDC?

Dr. HOUK. The moneys for the contractual portion, the moneys to do the interview and to do the physical examination, have already been awarded through 1984 appropriations when they come in. If it is decided not to do the Agent Orange study, those moneys—some of those moneys will ultimately revert to the Treasury.

We are funded through the Veterans' Administration of our annual costs that we have to incur a year for our staff of 50 and the various kinds of things to do this. We have had no difficulty with the Veterans' Administration in providing us the money that we have asked for to do what is necessary for the analysis and our in-house costs for this study, and we anticipate no difficulties of asking the Veterans' Administration to include that in their budget request. We have gotten all of the money that we have asked for.

We take seriously our charge of the public trust, of expending funds correctly. I would like to say that I am extremely proud of the manner in which these funds have been spent and used, that had we not done the procurement process, instead of 1984 costs, we would be now in 1988 costs and the Congress would have to be considering appropriating additional moneys for the new studies.

The point I would like to emphasize to the committee again, with my famous "2 weeks" statement, I have no apologies to make. Within 2 weeks of the time that that statement was made, we had gathered a staff of about 10 of my best people, literally sat them in a room, literally locked them up—they worked weekends, late afternoons and stuff—and within 2 weeks we had the basic outline of the protocols for the three studies put together. It was that outline that was able to be filled in and to come out to the overall protocol design.

Mr. ROWLAND OF CONNECTICUT. Thank you very much.

Thank you, Mr. Chairman.

Mr. DASCHLE. Thank you, Mr. Rowland.

Dr. Houk, that's almost like saying you designed the name of a book and then took 5 years to write it. It doesn't really matter whether we had a protocol or not if the book hasn't been written yet.

I would go back to a concern that Mr. Rowland very ably laid out with regard to priorities, and it goes back to an earlier concern that I expressed with regard to the real attention this issue has been given in CDC.

Dr. Mason, you certainly come to this committee with credibility, and Dr. Houk comes with a great deal of expertise on the issue. But when you say this has had the "highest" priority, you really defy that credibility somewhat. I look at the record. I see this constant delay. I note the fact that you have had numerous directors in charge of this study. The turnover has been quite significant—In fact, how many different directors have there been since you were commissioned with this responsibility?

Dr. MASON. Dr. Houk has been there from the beginning to the end. Down in the ranks, burnout, discouragement, frustration, has taken its toll because of the difficulties——

Mr. DASCHLE. I can understand. But how many study directors have you had?

Dr. HOUK. The Agent Orange projects, I think three. Dr. Erickson was the first to complete the birth defects study, now part of this. At the completion of the birth defects study, he asked to be relieved because his professional interest is in birth defects in children. He was then replaced by Dr. McGee, and then Dr. Laid, when Dr. Laid became chief of the division in which the Agent Orange projects are working, are being conducted.

Mr. DASCHLE. I don't know what your record is in other areas, but it is hard for me to believe that, given the time delay, given the turnover, and given the lack of any kind of significant accomplishment over this long period of time, you can honestly say to this committee that this has had the "highest" priority. I think it may be safe to say you have given it fair consideration, but I don't think you should do yourself the injustice of attributing CDC's credibility to this study and say, in effect, "we can't do any better than this."

I really question that. In fact, I challenge it, because I don't think CDC deserves merits that. You're better than that, and this study doesn't indicate the quality of work that CDC is normally capable of doing.

I know Mr. Ridge had some additional questions and I will turn the time over to him.

Mr. RIDGE. Thank you, Mr. Chairman. I will be brief. I do have a couple of additional questions and would like to submit even further questions in writing.

I want to thank you gentlemen for your candor and your professionalism. It is obviously a very difficult scientific question and it is a highly emotional one as well for the Members of Congress. We appreciate your indulgence during this hearing.

Would you tell me the degradation rate of the toxic levels of the dioxin, once put into the environment after spraying?

Dr. HOUK. It was originally thought that the half-life of dioxin in soil was less than a year. From Missouri, however, in areas that were sprayed in 1971, the level of dioxin detected in that soil in 1971 was precisely the same as detected in 1984. That probably is because of the manner in which it was sprayed, with a solvent in oil. If oil is not used, such as some areas of New Jersey, the half-life of the soil is very significantly less than 10 years. We don't know precisely what it is, but it is less than 10 years. If dioxin is laid down in a solvent, such as would be used with herbicides, there is pretty good evidence that its half-life in soil is in the decades.

Mr. RIDGE. Fine.

Recognizing your efforts to scientifically validate those veterans who were exposed and nonexposed, as I understand from your testimony, you have no difficulty in identifying nonexposed veterans; that part of the sample you have and you're comfortable with, right?

Dr. HOUK. One of the difficulties, as Mr. Christian will probably tell you later, in being able to get an individual exposed or unexposed, one has to have knowledge of that individual's whereabouts on each of the 365 days per year that the individual served in Vietnam. Part of the difficulty is in filling the gaps and imputing on the days on which you have no information. If it were very high exposure or a lot of exposure, that would become less difficult than

with relatively low exposure because of the misclassification. If we're going to show diffrences in health effects, they have to show the difference of someone exposed and someone not exposed. If you don't have clean cohorts—and by clean, I mean individuals where there is not misclassification on those days—then you may show some abnormalities that have no meaning, or you may not show abnormalities when, in fact, they are there. It is important to keep the misclassification of groups in doing epidemiologic studies to the absolute minimum.

Mr. RIDGE. Is there a particular scientific reason that you don't use men who may have been in the Navy or the Air Force in the South China Sea, those who may have moved in and out of Thailand or Japan who were involved in Vietnam, who you can absolutely confirm may not have been in the country for 14 days during their entire tour, or who may have been in and out of fire bases but never exposed to the exterior?

Is there a reason that these men are not used?

Dr. HOUK. As Dr. Mason said in his testimony, it is necessary that these people differ only in their exposure to Agent Orange, and while all other risk factors are the same. We opted to use draftees, one term only, between the years 1968, or 1967 and 1968, because those were the years that the combat experience was relatively the same. The combat experience, we are told by the experts, of 1967 is quite different from 1970 and 1971. We used draftees, and they were chosen for the Vietnam experience—the MOS's. The Army and Mr. Christian said their going to Vietnam or not going to Vietnam was simply luck, the toss of a coin, if you will. We would not have taken the Vietnam experience of picking people who had MOS's that most likely would serve in Vietnam with that MOS.

It is very carefully crafted to keep each and every of the nonexposure variables the same.

Mr. RIDGE. If you're looking for a draftee that was 11 bravo, that was drafted in 1968—while I was in the service, I never volunteered for anything.

Dr. HOUK. As I mentioned to Miss Kaptur, we don't accept volunteers.

Mr. RIDGE. I understand.

Dr. HOUK. It would bias the study.

Mr. RIDGE. I understand.

Finally, from your insistence and your persistence—and I understand it—to run a scientifically satisfactory sample, what minimal documentation do you accept or do you demand from Mr. Christian to confirm and corroborate the minimal 14-day exposure of veterans to Agent Orange? What minimal documentation do you need?

Dr. HOUK. We have asked Mr. Christian and he has agreed to provide that, where he can. This is one of the difficulties of some of the gaps that need to be filled in, of knowing where the individual is each of the days that he served in Vietnam. It is not difficult to identify companies and know where the company was every day; that is relatively easy—it's not easy, it's a difficult job, but Dick and his people have done it masterfully well.

The difficulty is identifying each of those individuals in that company, because those individuals may have been separated by 20 kil-

ometers from the record of their location where the company was. Again, the records were put together for purposes other than doing an epidemiologic study, and the fact that we are to the point where we're having difficulty identifying exposed and nonexposed people is a real tribute to the people who were working with the records. Otherwise, we could have assumed everybody was exposed if we had not been as careful—and by "we", I mean the whole system, Mr. Christian and our folks and everybody. We could have chosen people and we would have maybe had some very bad science, and bad science then would have come to the Congress to make policy on, which is not a very good idea of using bad science.

Mr. RIDGE. I appreciate that. Thank you very much.

Thank you, Mr. Chairman.

Mr. DASCHLE. Thank you, Mr. Ridge, and thank you, panel members.

Unfortunately, I will have to conclude this hearing within a half-hour, and we have two witnesses yet to come before the committee. I would like, if I could, to divide the remaining time between the two.

Mr. Richard Christian is the next witness. I would like to call him to the table. He is the Director of the U.S. Army and Joint Services Environmental Support Group. Mr. Christian, we are very pleased that you could be with us, and we thank you for joining us. I see you have some staff accompanying you.

The entire text of your statement will be submitted for the record. First I would like to have you limit your opening remarks to five minutes, and I would like you to confine them to the subpanel report, and then we will proceed with questions following that.

Before proceeding, if you wouldn't mind introducing the people accompanying you at the table for the record.

STATEMENT OF RICHARD S. CHRISTIAN, DIRECTOR, U.S. ARMY AND JOINT SERVICE ENVIRONMENTAL SUPPORT GROUP, DEPARTMENT OF THE ARMY; ACCOMPANIED BY MAJOR MAX TENBERG, CHIEF, SCIENTIFIC SUPPORT DIVISION; AND DONALD HAKENSON AND DOUGLAS CLARK

Mr. CHRISTIAN. Yes, sir. I am Richard S. Christian, Director of the U.S. Army and Joint Services Environmental Support Group, Department of the Army. I am pleased to appear before the committee to provide, in response to your request, ESG's research mission in support of the Agent Orange epidemiological study.

I am accompanied by Major Max Tenberg, on my right, who is the Chief of the Scientific Support Division, and Mr. Donald Hakenson and Mr. Douglas Clark, on my left.

As to the current interaction with the Centers for Disease Control, CDC was provided personnel data for over 20,000 study subjects, or what is termed the Vietnam Experience Study. This study covers all those factors, including Agent Orange, that may have contributed to potential ill health of the military who served in Vietnam.

On April 1, 1984, we began the research for both the Vietnam Experience Study and the major Agent Orange study. Changes

were frequently made in battalion tracking for the Agent Orange study and the Vietnam Experience Study. This required frequent adjustment of research to add, check, refine, assist, and massage the data. In July 1984, we were informed that 11 CDC contracts were signed, resulting in new time tables for ESG. Time tables and numbers of subjects and disqualification factors repeatedly changed over the ensuing months.

In November 1984, a major change in workload required ESG to research an additional 15 battalions and revise the selection process for Agent Orange study subjects. Due to lack of agreement on assumptions, Government scientists never approved an exposure model crucial to the study.

On September 12, 1985, ESG completed the only record of documented military spraying by helicopter, backpack, ground spraying, aborts and leaks. This document, now known as the "Services Herbs Tape", provided a second source, other than the Air Force Operation Ranch Hand, for the matching of units to Agent Orange spraying.

Defoliation spraying may have occurred at main base camps, fire support bases, and landing zones. Unfortunately, the records are not complete enough to substantiate the magnitude of these operations. In the 9th Infantry Division's area alone, there were about 365 such locations that might or might not have been sprayed. Yet, the records only show a total of 478 perimeter sprays for all of Vietnam during the entire war.

The Chairman of the Science Panel of the Agent Orange Working Group then tasked ESG to conduct a decisive pilot study on unit and troop exposure.

Accordingly, ESG researched and completed grid coordinate locations for all companies of seven combat battalions covering the period October 1, 1966 to March 13, 1969. ESG then matched the grid coordinate locations of each company by date against the Ranch Hand and Herbs Tapes to produce an exposure opportunity score for each company.

It should be clearly understood that ESG can identify a combat company's location on a given day. However, records do not permit the location of individuals in subelements or individual troops within these subelements at each location. ESG is not qualified to answer the scientific problems this creates. This is an issue the scientists must address.

In summary, over the past 3 years the military services have been scrutinized, scrubbed, and critically examined by distinguished groups of experts, such as the National Academy of Science, the Science Panel of the White House Agent Orange Working Group, and most recently, the Science Subpanel on Agent Orange Assessment. The records do not support continuance of the Agent Orange epidemiological study; that is, a study based solely upon the use of military records to select cohorts on men potentially exposed to Agent Orange. Mr. Chairman, we are proud of our work.

I will be happy to answer any questions that you have.

[The statement of Richard S. Christian appears on p. 86.]

Mr. DASCHLE. Thank you. Mr. Christian, for your succinct statement.

I would be interested in knowing how you could be so concerned with Army records when you and the subpanel's consultant, General Murray, both say that your location methodology is reliable.

Mr. CHRISTIAN. That's correct. General Murray examined the Environmental Support Group operation, all phases, including the research effort, and the quality of the personnel, and he found ESG to be the best.

Mr. DASCHLE. If expert Air Force advice would permit you to determine potential exposure of troops with a wider spray pass, say 6 kilometers, would you be inclined to reconsider your position on going ahead with this study?

Mr. CHRISTIAN. No, sir. The Ranch Hand records are the best records that are available. General Murray verified this fact when he examined those Air Force records. I would not be able to modify my position.

Mr. DASCHLE. But what if we expanded it—that's what I'm asking—from 2 to 6, or 2 to 8?

Mr. CHRISTIAN. The tighter the criteria, the more difficult it is for us to select study subjects. If you expand the study to 300 battalions—and General Murray recommended this as one of his alternatives in the report—it might be possible.

The problem that we have is that we're trying to make a scientific laboratory test out of combat operations and it is just not possible. We are restricted to selecting cohorts of a certain grade, from grade E-1 to E-5, and they must have served in the unit 180 days or more. If an individual served 179 days, he was disqualified. If he transferred out of Vietnam and landed in France, he was disqualified.

All of these qualifying factors that the scientists have put on us—and maybe they're necessary; we're not scientists—make it extremely difficult for us to respond to this issue.

Mr. DASCHLE. Do you think those constraints are reasonable?

Mr. CHRISTIAN. I can't answer that question, Mr. Daschle, because I'm not a scientist.

Mr. DASCHLE. Well, tell me what you think. I know you're not a scientist.

Mr. CHRISTIAN. I feel that there are restrictions of the grades and the time spent—and I'll explain both. Every person that served in Vietnam from the grade of private to general may or may not have been exposed. I and my staff do not understand why there is a requirement to have certain grades.

Also, as far as the requirement for an individual to be in a unit 180 days, quite frankly, if he was in a unit 15 days, and we could get him exposed to Agent Orange, that would seem to be sufficient for me.

Mr. DASCHLE. It sure would be for me, too. I mean, it seems to me that you're being told to submit a list of people potentially affected who are required to fit some criteria that really sound too narrow. I can understand where you would want a random sample, but you have been denied the opportunity to really provide a random sample by the constraints you've been given, would you not say, even though you're not a scientist?

Mr. CHRISTIAN. Yes, sir.

Mr. DASCHLE. You have enlightened us, and I appreciate that.

Mr. Rowland?

Mr. ROWLAND OF CONNECTICUT. No questions, Mr. Chairman.

Mr. DASCHLE. I have no further questions at this time, Mr. Christian, but I appreciate it very much. I am grateful for your statement.

Mr. CHRISTIAN. Surely. Thank you, Mr. Chairman.

Mr. DASCHLE. Our next witness is Miss Hellen Gelband, Director of the Special Projects office of the OTA Health Program, and Agent Orange Project Director of the Office of Technology Assessment.

Miss Gelband, in addition to whatever specific remarks you have—and I would be grateful if you could keep them somewhat brief—I would like you to address this question of defining too narrowly the exposure element of the study. If you could elaborate any more on what was said to the panel by Mr. Christian, I would be grateful to you for that.

Please proceed. The entire text of your statement will be submitted for the record.

STATEMENT OF HELLEN GELBAND, DIRECTOR, SPECIAL PROJECTS, AND AGENT ORANGE PROJECT DIRECTOR, OFFICE OF TECHNOLOGY ASSESSMENT

Ms. GELBAND. Thank you for the opportunity to appear here today. I am Hellen Gelband from the Office of Technology Assessment.

Public Law 96-151 specifies that studies mandated by that law be conducted in accordance with a protocol approved by the Director of OTA and that OTA monitor the conduct of any such studies. This responsibility includes the Agent Orange study.

The ability to do an Agent Orange study hinges on assembling groups of men who are different with respect to exposure but similar in as many other ways as possible. And we have heard quite a lot of about that this morning. I would like to summarize the efforts over the past 3 years to identify the requisite groups of men.

In June 1983, OTA reviewed protocols for the three studies planned by CDC, including the Agent Orange study. OTA stated in its review of that document: "It is still possible that studying associations between health effects and Agent Orange exposure may not be possible because the records will not provide information for meaningful exposure classification."

In February 1984, OTA approved the general structure of CDC's revised protocols, while noting that the details of a method for classifying men had not yet been worked out.

CDC's first report about exposure assessment to OTA came in February of 1985. At that time CDC proposed a major change from what was described in the protocol. The battalion, rather than the company, would be the unit of exposure. OTA's advisory panel met in February 1985, to review the CDC report, and OTA reported to Congress in April. We found that the battalion approach was unacceptable because of the overwhelming amount of misclassification—that is, categorizing men as exposed who really weren't, or calling men unexposed who were actually exposed—that would be introduced by that approach.

As a follow up to our February panel meeting, OTA staff met with Mr. Christian and his colleagues at the ESG to discuss the problems CDC had raised about the lack of information in the records for determining locations for companies. It appeared that, in fact, ESG could locate companies if CDC would agree to using different types of information than they had specified originally. ESG thus developed the approach that was used in the pilot study that has been called the "contextual" approach to fill in gaps in location data.

In late September 1985, OTA Director John Gibbons wrote to the congressional committees, expressing concern that no new information about CDC's exposure assessment plans had come to OTA, but that CDC had not changed their plans for interviews of study participants to begin in January. Subsequently, OTA received a series of documents between November 18 and December 13 and held an advisory panel meeting on December 14 to review the material, with the hope that the plan would be far enough advanced to allow undertaking the interviews with confidence that the study would proceed on a sound footing.

At that time CDC did not comment on the unexpectedly low level of exposures represented by the data they presented, and they evinced no skepticism about the viability of the study. OTA did, however. The serious problems still existing led to OTA's recommendation that "no major new phase of the study should be undertaken before new design and exposure assessment methods are found acceptable" by OTA.

In early January 1986, Dr. Mason wrote to the committees of Congress, responding to OTA's assertions. His letter stated that the design changes noted by OTA had been presented to the AOWG Science Panel and that the Science Panel "supported the design changes." His letter stated CDC's intent to proceed with the interviews as planned.

Both the House and Senate Veterans' Affairs Committees wrote to Secretary Bowen expressing concerns about the study. While CDC based its decision to go ahead with the interviews on fiscal considerations, as described in Dr. Mason's letter, the Congress voiced its concern about "the implications of interviewing subjects for the study, only later to advise them that the study is not going forward." Such an action could be interpreted as an attempt to cover up early findings.

In response to the committees' letters, further interviewing was not carried out. We do not know how many interviews actually took place, if any.

To date, OTA has not received a new protocol for the Agent Orange study. OTA was not involved in the exposure subpanel activity, but we did participate as observers at the time of the science panel review of the subpanel report. We have not received their report officially.

Recently, we received a letter from Under Secretary Newman requesting OTA's permission for CDC to prepare a protocol for a validation study, which Dr. Mason described in his testimony. OTA does not have the authority to grant such approval and we replied to that effect. As soon as a protocol is developed, however, we are ready to review it.

I will be happy to answer any questions now.

[The statement of Hellen Gelband appears on p. 92.]

Mr. DASCHLE. Thank you, Miss Gelband.

Mr. Rowland.

Mr. ROWLAND OF CONNECTICUT. Thank you, Mr. Chairman. I just have one question.

Quoting from your statement, you said something to the effect that the Office of Technology Assessment may decide that the problems of deciding on exposure are so overwhelming that it is impossible to study the possible effects of Agent Orange; is that correct?

Ms. GELBAND. Yes.

Mr. ROWLAND OF CONNECTICUT. So, in essence, it is indeed an arm of Congress that more than a year ago raised the possibility that a scientific study might not be possible?

Ms. GELBAND. That's right.

Mr. ROWLAND OF CONNECTICUT. Would you like to make any other comments on that?

Ms. GELBAND. I think we, as well as the Agent Orange Working Group, thought that was a possibility, although we really didn't have all the information to make an evaluation until fairly recently. I think the validation study, the pilot study that was carried out by Mr. Christian's group and the Agent Orange Science Subpanel, has provided a good deal of that information and have corroborated what we suspected then.

Mr. ROWLAND OF CONNECTICUT. We have spent a great deal of time this morning talking about resources and finances and budget priorities—one of the questions I brought up earlier.

Do you feel that your office has had the proper resources, the dollars, and the priority establishment to aid us in this study and what we have been working on today?

Ms. GELBAND. Yes, I do. We have had an advisory panel constituted since, I think, 1981, and they meet when we feel it's appropriate. It is usually about twice a year. We keep in touch with them.

Since we are not actually doing the study, we don't have ongoing data-collection responsibilities or anything of that nature. And I think we've had adequate resources.

Mr. ROWLAND OF CONNECTICUT. Do you feel there is anything that this committee or this Congress can do to enhance your abilities to continue your work in that manner?

Ms. GELBAND. I think the committees and the staff in particular have been very supportive of us. I think we would like to be as unobtrusive in the process as we can. In fact, we found ourselves being much more intrusive than we ever had dreamed we would be. We didn't really see ourselves as having to make decisions that no one else seemed to be willing to make. We hoped everything would go well and that we would be able to say yes, this is being done very well.

Mr. ROWLAND OF CONNECTICUT. I'm sure many of my colleagues on the committee feel the same way. We would like to thank you for the efforts you have made and appreciate all the work you have done.

Mr. Chairman, I would also ask unanimous consent that Mr. Ridge, who unfortunately wasn't here for Mr. Christian, if he could

be allowed to submit questions in writing, it would be greatly appreciated.

Mr. DASCHLE. Without objection.

[See p. 134.]

Mr. ROWLAND OF CONNECTICUT. Thank you, Mr. Chairman.

Mr. DASCHLE. Thank you, Mr. Rowland.

Miss Gelband, I would like you to respond to my request as you were being introduced, with regard to the comments made by Mr. Christian. His comment, which I thought was a very interesting one, was that the criteria set out by CDC was really too narrowly drawn—the time in the field, the location, things of that sort. That really appeared to him and, from a layman's point of view, to me, to be too confined, and perhaps too impractical.

But what is your view?

Ms. GELBAND. I think the criteria were appropriate, actually, and I will give you one example.

For instance, if you took a man in the exposed cohort who only spent 15 days in a particular unit and then for some reason was gone, yes, he might meet the criteria for exposure. But you're going to have to have another group that is similar in all other ways.

Now, if you took men who served for 15 days in a unit and weren't exposed, you don't know what happened to them after they transferred out, so it is possible that they were very heavily exposed during the rest of the year. But there is a chance that men who served only 15 days are somehow different from men who served an entire year in a particular unit. I mean, maybe there is some reason why that man was only there 15 days that was health related. If you use different criteria when you're setting up your exposed group, if a man only had to be there long enough to be exposed, but if in your unexposed group you say "we have to know where that guy was every day, because even a single day where we don't have him tracked he may have been exposed", you're setting up different criteria for your two groups, and that's a basic tenet of epidemiology, that you really have to try and match as closely as possible.

Mr. DASCHLE. Why couldn't you have those two groups, though, be two separate cohorts? I mean, you have a short exposure cohort and a longer exposure cohort. I have to believe that there are few people who were actually exposed for elongated periods of time given the situation.

Ms. GELBAND. Well, I think the example Mr. Christian brought up was not a 15-day exposure but a man who came to Vietnam in a particular unit and was exposed in the first 2 weeks he was there, but then transferred from that unit into another area of Vietnam, or maybe we don't even know where—we can find out—but maybe in an area not connected with the study. We don't really know what happened to that man, and he doesn't meet the other criteria for our study, even though he was exposed.

You go to the other side and you have a man who arrives in Vietnam, stays in one unit for 2 weeks, and then transfers. You don't have any further information about him, but he wasn't exposed. Not knowing what happened to him during the rest of the year he was there means that he could well have been exposed as much as this other man. You would have to track him for the

whole year, whereas you would only have to track the other men for 2 weeks.

Now, there may just be differences between men who transfer out after 2 weeks and go to another unit versus men who stay with the same unit and therefore are tracked for the whole time. It is really a matter of trying to make sure that you're not introducing any biases between these two groups.

Mr. DASCHLE. It seems to me that in the effort to avoid bias we have almost entered a new bias, and that is a bias in favor of those who may have been there a long period of time, which obviously very, very narrowly, then, constrains this whole effort, because I really question whether there are that many people who would fit that definition. You can more readily understand their inability to come up with a proper sample. But it seems to me we're defeating the purpose if that's the case.

There was a question to be asked by counsel that I really would like to ask in writing, about what opportunities there are to broaden the base, broaden this whole study out somewhat.

Ms. GELBAND. Well, the general problem that you run into—and we have certainly thought about this, and it may be that there are some ways that that could be done. The general problem is, if you start taking more people in the possibly-exposed group, just to capture people you're pretty sure were exposed, you end up with more people who really weren't because your criteria are fairly loose.

If you compare them with another group of people who weren't exposed, then even if there is something going on in the heavily exposed men, you just won't see it because it will be swamped by the unexposed people you have included in you "exposed" group. So the criteria have to be drawn somewhat tightly so you make sure that most of the people in the group actually were exposed. It's a balance.

Mr. DASCHLE. Last December 19 you notified this committee that CDC was proceeding with a study design "radically different" from the one OTA had approved. The central issue in that notification was the question of exposure as a continuous variable.

How do you think that reflects on the cooperation between CDC and OTA?

Ms. GELBAND. Well, I can comment on what I think it meant for the study.

Mr. DASCHLE. Well, I would like to have you comment on what it means between OTA and CDC's relationship.

Ms. GELBAND. Well, I'm not sure I understand the question.

Mr. DASCHLE. Well, as you know, Public Law 96-151 requires that there be very close cooperation between CDC and OTA. Here you approve a protocol, and then CDC comes up with something radically different, as you have indicated to the committee.

Ms. GELBAND. Yes.

Mr. DASCHLE. That is a warning sign to me that something isn't very harmonious, that there isn't that kind of cooperation that we had envisioned in the law. I am simply asking for you to elaborate on what that means.

Ms. GELBAND. Well, I wouldn't characterize our association as harmoneous. But I think, in part, any organization who is being watched over is not going to like that too much.

We have not had a great deal of communication from CDC, and it has been sometimes difficult to find the right person to talk to. There have been a number of study directors.

Mr. DASCHLE. Have they indicated to you an interest in communicating? Have they asked for meetings to relay the changes and the causes for delay and the range of issues we have talked about this morning?

Ms. GELBAND. We have initiated most of the requests for information. It was our request in September that prompted the November report.

Mr. DASCHLE. Have they responded with each request?

Ms. GELBAND. In some way. Recently, we have actually had good response on another issue having to do with the Vietnam Experience Study and—

Mr. DASCHLE. Dr. Mason had indicated this whole issue has the "highest priority" in CDC. Would you verify that?

Ms. GELBAND. I have no way of knowing that.

Mr. DASCHLE. Excuse me?

Ms. GELBAND. I have no way of knowing that.

Mr. DASCHLE. Well, you are the oversight agency, are you not?

Ms. GELBAND. For this study.

Mr. DASCHLE. For this study.

Would you say that this study has received the kind of attention and thoroughness that would rate it as having the highest priority?

Ms. GELBAND. I think there have been a number of instances of inefficiency, and I believe we could have been somewhat farther ahead than we are now. I'm not sure whether that's priorities or bureaucracy or just what. I don't know the internal workings of CDC.

Mr. ROWLAND OF CONNECTICUT. Would the gentleman yield on that point?

Mr. DASCHLE. I would be happy to yield.

Mr. ROWLAND OF CONNECTICUT. Just to follow up on that, are you basically saying you don't know what the other studies are and you're not overseeing the other studies; therefore, you can't determine what level of priority it's at?

Ms. GELBAND. That's part of it, the other non-Vietnam studies, yes.

Mr. DASCHLE. What does the exposure issue mean for the newest proposal of blood marker exposure verification?

Ms. GELBAND. I think the proposal in the concept paper prepared by CDC is worth examining. We will need a fair amount of more detail and a real protocol before we could comment on it. It is certainly consistent with the findings of the subpanel, as Dr. Mason characterized them today.

We still will be stuck with trying to come up with a records-based definition of exposure to validate with the blood test, and so I think it is important that in any protocol all of the information that's been generated by Mr. Christian and the Science Panel subpanel be used, and that any records-based definition be consistent with the facts as we know them now, which are different than the facts that we had a year ago. We will be happy to review it and see if it appears promising. It certainly is a rational approach.

Mr. DASCHLE. Is there any inclination at this point on what to do?

Ms. GELBAND. Not until we see the data from the first phase of that study and see the definitions from the records that CDC is proposing.

Mr. DASCHLE. Well, thank you, Miss Gelband, for your contribution to the committee and to our understanding.

Mr. Rowland?

Mr. ROWLAND OF CONNECTICUT. Thank you, Mr. Chairman. I just want to follow up with one question.

Dr. Mason indicated that if this new study procedure fails, if it doesn't work, that, in essence, they will be at a dead end. Do you agree with that thought?

Ms. GELBAND. Unless someone comes up with another brilliant idea, I'm afraid I agree with that.

Mr. ROWLAND OF CONNECTICUT. Thank you.

Mr. DASCHLE. I don't know. Frankly, I'm a little disappointed in OTA. I would have hoped OTA could have been more aggressive in its oversight role. It seems to me that OTA really hasn't done a very effective job in ensuring that things of this kind are brought to the committee's attention or really brought out for the public record. I would hope that in the future we could take a look at location, we could take a look at Herbs Tapes, and we could take a look at the requirements of CDC in the field—the criteria they used.

I think, if anything has come out of this hearing this morning, it is that we have really got a lot of loose ends. In part, that is the fault of CDC, and in part, it's OTA's fault. I don't think OTA has done its job very effectively. I would hope that you could take that message back. Because we're going to look at this again. We have a responsibility under the law, and OTA has a responsibility under the requirements of that law, to ensure proper oversight.

I think that the same could be said with regard to priority about OTA as it was with CDC. This apparently doesn't have a very high priority at OTA, and I would hope in the future OTA could give it a higher priority and get a little tougher and come up with a little more forceful approach to this thing. We want to see it.

We will be holding another hearing at some point in the future, to see if you can give us a more substantive, forceful analysis of what is happening. But certainly when it comes to these criteria, as Mr. Christian pointed out, we've got a lot to look at, and we're just not going to let this thing go.

I would like nothing more than at long last to have something definitive. But we have waited for 7 years, and it has really almost made a mockery of this whole process. I don't know whether to start over or whether to really hold weekly hearings until we have resolved some of these things. If I were chairman of this subcommittee, I think we would consider that. I'm not, and all we can do is make recommendations.

Clearly, after this long a period of time, and with this little substantive analysis provided to this committee, and with this foot dragging that we see constantly with regard to the whole range of issues we have discussed this morning, I have to contain my frustration as I consider the information presented this morning.

Mr. Rowland, did you have additional comments?

Mr. ROWLAND OF CONNECTICUT. Mr. Chairman, I just wanted to make a comment.

I strongly agree with much of what you said, but I think for clarification purposes OTA's responsibility under the mandate was to oversee the protocol portion of the study, if my information is correct. Is that true?

Ms. GELBAND. It is both to approve protocols and to monitor the conduct.

Mr. ROWLAND OF CONNECTICUT. Well, I think it is important to make that clarification. But, indeed, I share your concerns about the entire process. I think OTA has done a fairly good job. But I guess there is such a high degree of frustration here that we're all going to share it. You're a "creature" of this Congress and you're going to share it with us, I suppose.

Thank you very much.

Ms. GELBAND. I'll take some back to my Director.

Mr. DASCHLE. Very good. Thank you, and I thank all the other panel members.

Ms. GELBAND. Thank you.

Mr. RIDGE. Mr. Chairman, if I could just make one final observation.

Mr. DASCHLE. I'm sorry. Absolutely.

Mr. RIDGE. That's all right. I'm used to being ignored.

(Laughter.)

Mr. DASCHLE. I'm sorry, Mr. Ridge.

Mr. RIDGE. I know it wasn't intentional.

Mr. DASCHLE. For your information, Mr. Rowland asked that the questions you had hoped to ask Mr. Christian be inserted in the record for response, and we have taken care of that.

Mr. RIDGE. I appreciate that protection and that opportunity.

I have just a thought, a tag-along comment to your observations, which I think are accurate. I think it is appropriate that we indulge in some self-criticism because when you criticize OTA you are basically criticizing the Congress of the United States, inasmuch as they are an arm of the legislative branch. I think, given the expression of the high profile and concern among those who chose to appear today, and of the subcommittee's formal chairman, who is not here, we must be even more vigilant than we have been since the inception of 1979.

I look forward to working with you and other members of the subcommittee to be a lot more vigilant, and to give, to the extent we can, better direction to OTA and to the study.

I thank you for protecting my right to ask questions.

Mr. DASCHLE. Thank you, Mr. Ridge. We are pleased to have your contribution, which has been a very valuable one this morning.

The subcommittee stands adjourned.

[Whereupon, at 12:07 p.m., the subcommittee was adjourned.]

STATEMENT OF THE HONORABLE ROBERT W. EDGAR

CHAIRMAN

SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE

AT A HEARING ON THE

STATUS OF THE AGENT ORANGE STUDY

JULY 31, 1986

THE HEARING WILL COME TO ORDER.

THIRTEEN TIMES SINCE 1978 THE HOUSE VETERANS AFFAIRS COMMITTEE AND ITS SUBCOMMITTEES HAVE HELD HEARINGS ON THE SUBJECT OF AGENT ORANGE. IT IS TIME AGAIN FOR US TO HEAR ABOUT AGENT ORANGE. WE WANT TO HEAR TODAY FROM THE PEOPLE WHO ARE DIRECTLY INVOLVED IN THE SCIENCE OF THE QUESTION OF AGENT ORANGE. IT IS TIME FOR THEM TO TELL US THE STATE OF AFFAIRS OF THE STUDY MANDATED IN PUBLIC LAW 96-151.

AT THE VERY OUTSET, LET ME CLARIFY THAT THE AGENT ORANGE STUDY WHICH IS THE SUBJECT OF TODAY'S HEARING IS ONE OF THREE STUDIES BEING CONDUCTED BY THE CENTERS FOR DISEASE CONTROL. IT IS THE SPECIFIC PURPOSE OF THE

AGENT ORANGE STUDY TO TRY TO DETERMINE IF A LINK BETWEEN EXPOSURE TO DIOXIN, THE CONTAMINANT IN AGENT ORANGE, AND ANY LONG-TERM HEALTH EFFECTS EXISTS. THE OTHER TWO STUDIES ARE THE VIETNAM EXPERIENCE STUDY WHICH WILL PROVIDE INFORMATION ABOUT THE HEALTH STATUS OF VIETNAM VETERANS AND THE SELECTED CANCERS STUDY WHICH WILL PROVIDE INFORMATION ABOUT THE OCCURENCE OF CERTAIN TYPES OF CANCER IN VIETNAM VETERANS.

I DO REGRET THAT THIS HEARING MUST INQUIRE INTO THE STATUS OF THE STUDY RATHER THAN TO REVIEW RESULTS OR TO RECEIVE A PROGRESS REPORT INITIATED BY THE STUDY TEAM. WE KNOW THAT IT IS A DIFFICULT STUDY IN EVERY ASPECT. IT REQUIRES SOME NEW APPROACHES AND

COMPLEX DECISIONS.

NO ONE EXPECTED THE STUDY TO BE EASY. WE DID EXPECT, HOWEVER, THAT THE MAJOR PLAYERS WOULD KEEP THIS COMMITTEE AND THE CONGRESS INFORMED OF PROGRESS AND PROBLEMS. IN FACT, ONE PURPOSE BEHIND THE STATUTORY REQUIREMENT THAT THE OFFICE OF TECHNOLOGY ASSESSMENT APPROVE THE PROTOCOL AND MONITOR THE CONDUCT OF THE STUDY WAS TO PROVIDE A CLEAR ROUTE FOR INFORMING THE CONGRESS AND THE AMERICAN PUBLIC ABOUT HOW THINGS WERE GOING. FORTUNATELY WE HAD THE REQUIREMENT OF PARTICIPATION BY THE OTA, BECAUSE WITHOUT THAT ORGANIZATION WE WOULD NOT HAVE BEEN INFORMED OF THE MOST RECENT SERIES OF EVENTS RELATED TO WHAT HAS ALWAYS BEEN THE CRUX OF THE AGENT ORANGE STUDY.

THE CRUCIAL PROBLEM OF THE STUDY IS HOW THE POTENTIAL EXPOSURE TO THE DIOXIN IN AGENT ORANGE IS TO BE QUANTIFIED FOR PURPOSES OF THE STUDY. THAT WAS KNOWN TO BE ESSENTIAL IN 1979 WHEN PUBLIC LAW 96-151 WAS ENACTED. THAT WAS KNOWN IN JANUARY OF 1983 WHEN THE CENTERS FOR DISEASE CONTROL IN THE DEPARTMENT OF HEALTH AND HUMAN SERVICES GAINED RESPONSIBILITY TO CONDUCT THE STUDY. THAT IS KNOWN TODAY IN 1986 AND WE HAVE HAD TO CALL YET ANOTHER HEARING TO ASK ABOUT IT. WE HAVE NOT DEMANDED MIRACLES, BUT WE ALL DESERVE AN UPDATE.

ON JANUARY 10 OF THIS YEAR, THE CHAIRMAN AND RANKING MINORITY MEMBER OF THIS COMMITTEE

JOINTLY SENT A LETTER TO THE SECRETARY OF HEALTH AND HUMAN SERVICES EXPRESSING THE CONCERN OF THE WHOLE COMMITTEE ABOUT THE PROGRESS OF THE STUDY. WITH THE LETTER WENT A REMINDER THAT THE LAW REQUIRES THAT A COMPLETE PROTOCOL BE APPROVED BY OTA BEFORE THE STUDY BEGINS. THE CHAIRMAN AND RANKING MINORITY MEMBER OF THE SENATE COMMITTEE ON VETERANS AFFAIRS SENT A SIMILAR LETTER. INFORMATION WAS REQUESTED IN BOTH LETTERS ABOUT THE PROGRESS OF THE PROTOCOL AND A TIMETABLE FOR THE NEXT STEPS TO GET THIS STUDY UNDERWAY. ON MAY 7 OF THIS YEAR ANOTHER LETTER WENT FROM THIS COMMITTEE TO THE SECRETARY OF HHS. THE ONLY ANSWERS WE

HAVE RECEIVED ARE REASSURANCES THAT THE PROBLEMS ARE BEING WORKED ON AND THAT WHEN SOMETHING IS KNOWN, WE WILL BE INFORMED.

THAT'S NOT GOOD ENOUGH. I CAN NOT FORGET THAT I WAS PRESENT IN THIS ROOM ON SEPTEMBER 15, 1982 FOR A HEARING ON AGENT ORANGE. THERE WAS A QUESTION ABOUT WHO WAS DRAGGING THEIR FEET ON THE AGENT ORANGE QUESTION. THE RESPONSE FROM DR. HOUK OF THE CENTERS FOR DISEASE CONTROL WAS THIS: "IF I WERE RESPONSIBLE FOR THE DEVELOPMENT OF THE PROTOCOL, I WOULD GET A GROUP OF PEOPLE -- EPIDEMIOLOGISTS, LABORATORY PEOPLE, THE NECESSARY ONE .S. FROM WITHIN OUR OWN SHOP, AND OUTSIDE HELP IF WE HAD TO HAVE IT IF WE

DIDNT'T HAVE THE NECESSARY EXPERTISE -- PUT THEM IS A ROOM AND TELL THEM NOT TO COME OUT UNTIL THEY HAD ONE DONE AND THAT WOULD TAKE, IN MY ESTIMATION, MAYBE A COUPLE OF WEEKS."
WELL! THAT WAS ALMOST FOUR YEARS AGO AND WE STILL HAVE NO PROTOCOL. PERHAPS IT'S TIME TO LET THOSE PEOPLE OUT OF THAT ROOM SO THEY CAN TELL WHAT THEY HAVE DONE SO FAR.

I WOULD NOW LIKE TO RECOGNIZE JOHN PAUL HAMMERSCHMIDT, THE RANKING MINORITY MEMBER OF THE SUBCOMMITTEE AND FULL COMMITTEE, FOR ANY REMARKS HE MAY WISH TO MAKE.

THE FIRST WITNESS TODAY IS THE HONORABLE DON BONKER, THE REPRESENTATIVE FROM THE THIRD DISTRICT OF THE STATE OF WASHINGTON.

RECENT CHRONOLOGY OF EVENTS IN CDC AGENT ORANGE STUDY

JANUARY 1983	CDC GETS RESPONSIBILITY TO DESIGN AND CONDUCT STUDY WITH REVIEW BY OFFICE OF TECHNOLOGY ASSESSMENT
SUMMER 1985	HVAC STAFF HEARS OF PROBLEMS IN STUDY DESIGN REGARDING EXPOSURE ASSESSMENT AND THAT CDC IS WORKING WITH A "RADICALLY DIFFERENT DESIGN" THAN THE ONE CONDITIONALLY APPROVED BY OTA; TROUBLED WORKING RELATIONSHIP BETWEEN CDC AND ARMY ENVIRONMENTAL SUPPORT GROUP; TROUBLED WORKING RELATIONSHIP BETWEEN CDC AND OTA.
FALL 1985	HVAC STAFF CALLS MEETING OF SENATE AND HOUSE COMMITTEE STAFF, CDC, ESG, OTA TO DISCUSS PROBLEMS. SERIES OF WORKING MEETINGS AMONG VARIOUS ACTORS OCCURS BUT EXPOSURE ASSESSMENT PROBLEM IS NOT SOLVED.
JANUARY 1986	CHAIRMAN AND RANKING MEMBERS OF HOUSE AND SENATE VETERANS COMMITTEE WRITE SECRETARY OF HHS REQUESTING INFORMATION ON STATUS OF AGENT ORANGE STUDY; TIMETABLE FOR THE PROTOCOL AND STUDY; STATING THAT NO IMPLEMENTATION OF A STUDY CAN GO FORWARD UNTIL A PROTOCOL HAS BEEN REVIEWED BY OTA.
FEBRUARY 1986	RESPONSE FROM HHS SAYING THAT THEY ARE WORKING ON THE PROBLEM AND WILL LET US KNOW WHEN THEY'RE DONE.
MAY 1986	FOLLOWUP LETTER TO HHS FROM CHAIRMAN AND RANKING MEMBER OF HVAC AGAIN REQUESTING TIMETABLE AND STATUS OF STUDY.
APRIL 1986	ACTING ASSISTANT SECTRETARY FOR HEALTH (HHS) WHO IS VICE-CHAIRMAN OF AGENT ORANGE WORKING GROUP DIRECTS FORMATION OF SPECIAL SCIENCE SUBPANEL ON EXPOSURE ASSESSMENT. THE SUBPANEL DOES TWO THINGS: RESEARCH LITERATURE FOR INFORMATION ON WHAT MAKES SENSE IN TERMS OF EXPOSURE TO AGENT ORANGE AND RUNS A PILOT TEST OF ESG RECORDS OF PERSONNEL IN VIETNAM (MORNING REPORTS, ETC) AND HAS THEM REVEIWED BY RECORDS EXPERT (MAJOR GENERAL MURRAY).
MAY 28	SUBPANEL REPORT FINISHED AND SENT TO SCIENCE PANEL OF AGENT ORANGE WORKING GROUP.
JUNE 17	SCIENCE PANEL VOTES TO SEND SUBPANEL REPORT TO FULL WORKING GROUP.
JUNE 23	INTERIM RESPONSE TO MAY 7 LETTER SAYING HHS IS AWAITING RESULTS OF SUBPANEL REPORT.
JULY 15	AGENT ORANGE WORKING GROUP MAKES NO DECISION ON RECOMMENDATION OF REPORT.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

July 30, 1986

The Honorable Bob Edgar
Chairman, Subcommittee on
Hospitals and Health Care
Committee on Veterans Affairs
U.S. House of Representatives
335 Cannon House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

This is in reply to your letter of July 30, 1986 to the Chairman of the Domestic Policy Council Agent Orange Working Group. The letter requested a copy of the Report of the Science Subpanel on Exposure Assessment including the summary memorandum of the Subpanel Chairman and all of the report's appendices.

Because this document was generated by a White House Domestic Policy Council Working Group, I have forwarded your request to Dr. Ralph Bledsoe, Executive Secretary, Domestic Policy Council, The White House, for advice regarding the release of this report.

I will contact your office as soon as we have heard from Dr. Bledsoe on this matter.

Sincerely,

Robert L. Raclin
Chair Pro Tempore
Agent Orange Working Group

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

JL 30 1986

The Honorable Bob Edgar
Chairman
Subcommittee on Hospitals
and Health Care
Committee on Veterans' Affairs
House of Representatives
Washington, D.C. 20515

Dear Mr. Edgar:

This is in response to your letters to Secretary Bowen and Under Secretary Newman inviting them to testify at a July 31 hearing on the Agent Orange Exposure Study.

Dr. James O. Mason, Director, Centers for Disease Control (CDC) will be the lead witness for the Department and will also represent the Agent Orange Working Group (AOWG). He will be accompanied by Dr. Vernon Houk, Director, Center for Environmental Health, CDC, Mr. Ed Weiss, Acting Executive Secretary, and Dr. Carl Keller, until recently Chairman of the Science Panel, of the AOWG.

If we can be of further assistance please let us know.

Sincerely yours,

Ronald F. Docksai
Assistant Secretary
for Legislation

Tom Ridge

OPENING STATEMENT
CONGRESSMAN THOMAS J. RIDGE
COMMITTEE ON VETERANS AFFAIRS
SUBCOMMITTEE ON HOSPITALS & HEALTH CARE
JULY 31, 1986

First I would like to commend my colleague from Pennsylvania for calling this informational hearing on the Agent Orange study this morning. I commend him because there has been a great deal of confusion in recent weeks about the progress of this study, its status, and its future.

As the only enlisted combat Vietnam veteran serving in the House, I feel compelled to stress my support for the congressionally-mandated study on the health effects of Agent Orange. Despite the many roadblocks we've encountered in reaching final conclusions about Agent Orange, I believe without question that the study is workable, and that credible results can be obtained. The many advances we've made in technology and biochemistry in recent years provides an even greater opportunity to obtain conclusive and substantive results about the effects of Agent Orange.

Major hurdles remain for the Agent Orange study. The hearing today should provide us with valuable information about the design of a revised protocol, and I have every reason to believe that the men and women assigned to this task are making every effort to complete that design. But I want to stress that we've made a commitment to the men and women who served us so well and so unselfishly during the Vietnam conflict -- a commitment to find answers to so many questions about Agent Orange exposure. I commend the men and women on their work thus far, and I look forward to further progress on this long awaited study.

TESTIMONY OF THE HONORABLE DON L. BONKER

Before the Subcommittee on Hospitals
and Health Care

Hearing on Agent Orange Study

July 31, 1986

Mr. Chairman and Members of the Hospitals and Health Care Subcommittee, let me thank you for this opportunity to bring before the subcommittee concerns that I have about the Agent Orange Study being developed by the Centers for Disease Control. The issue of the health effects of Agent Orange exposure has been of great importance to Vietnam veterans in my District and I am grateful for this opportunity to give voice to some of their concerns.

Not being a member of the Veterans Affairs Committee, I have tried to address the needs of exposed veterans in two ways. Most importantly, I have worked with the regional Veterans Administration offices in Portland, Tacoma, and Seattle to be sure that Vietnam veterans receive the treatment they are entitled to under the provisions of P.L. 97-72. I have met with veteran groups to let them know that should treatment problems occur, they should let me know and I will help. Additionally, Chairman Montgomery has kindly offered the assistance of the Veterans Affairs Committee in this area and I am confident that with that assurance we can resolve any future problems in this area.

The second approach I have taken is to work with the Veterans Administration and the committee here in Washington, D.C. to bring to their attention some of the concerns made known to me by veterans in my District. That is the reason I am appearing before the subcommmittee this morning. As I

have become more deeply involved in this issue, I have come to believe that the resolution of this troubling legacy of the Vietnam War is long overdue.

For seven years, we in Congress have been struggling with the problem of how to address the needs of Vietnam veterans exposed to Agent Orange during their service in Southeast Asia. During those seven years, we have enacted three major laws focused on devising a method to measure the levels of exposure to Agent Orange and the nature of its health effects. We have also attempted to ensure adequate health care for veterans during the interim period until the studies are completed and Congress and the Administration can make a better determination of Federal responsibility.

Unfortunately, this process has dragged on over the course of seven years. Persistant questions still remain about the health effects of Agent Orange exposure and in many cases, Veterans have had problems receiving the care they're entitled to at Veterans' Administration hospitals. The Agent Orange study, which we'd hoped would provide conclusive evidence, has developed a clouded history of which the recent problems are only another chapter. In 1983, after problems with the VA, the responsibility for the study was transferred to the Centers for Disease Control, based partly on CDC's assurance that they easily would be able to complete such a study. Today, three years later, we are not only still waiting for the results of the study, but we are waiting for an acceptable method to be approved so that the Agent Orange Study can begin.

I am here this morning to say that it is not acceptable to promise a study without being sure it can be completed, as they appear to have done.

Furthermore, it is not acceptable to draw out the study, as CDC has done, and to provide so little information to Congress about why. I am alarmed by reports I have received of the study's problems and concerned that discussion of redesign of the protocol may be a solution that is politically expedient, but not one that contributes to the solution of the problem. I do not want to be in a position a few years down the road of asking what the point of spending millions of dollars was for a study that proves worthless. Like many of my colleagues, my staff and I work with veterans on a regular basis and we want to do everything we can to help them. Yet, I do not believe that we help anyone by making promises we can't keep.

I wish to emphasize that I am not insensitive to the enormity of the research task which has confronted CDC and the difficulty of designing this epidemiological study and I am pleased by their success with the Rare Cancer and Vietnam Experience studies. It is not my purpose to pressure them to adopt a protocol that will not yield scientifically valid results. But I am compelled to question the motive of the CDC for making these promises which now appear reckless and irresponsible. I am also concerned that we may lose sight of the message that this delay sends out to veterans suffering sometimes fatal health disorders--a message that the government is deliberately stalling the study rather than seriously addressing the urgency of their needs.

Since the study was first called for in 1979, let's remember that the U.S. government has evacuated two cities because of toxic contamination, Love Canal, New York and Times Beach, Missouri. In the case of Times Beach, one of the main health concerns was dioxin contamination--the byproduct of Agent Orange that concerns us all. Additionally, the seven chemical companies that

manufactured Agent Orange during the war, agreed to settle the wrongful injury case brought against them by thousands of Vietnam veterans for $180 million. While the chemical companies denied liability, a $180 million settlement to most people, especially Agent Orange veterans, seems a steep price for an innocent party to pay. Yet in spite of these events and other apparent admissions of serious health risks associated with dioxin exposure, Vietnam veterans are only entitled to a service connected disability if they suffered chloracne within 3 months of exposure. In their eyes, this represents a serious contradiction.

Over the past year, I have met with many veterans, some who are suffering from life-threatening cancers which they believe were caused by exposure to Agent Orange during their service in Vietnam. I do not claim the expertise to determine what the effects of Agent Orange exposure are and I know from personal experience that many times in life, good people suffer fatal diseases for reasons which we will never understand. But I do believe we have a responsibility to those who bravely served our country to do what we can to put their minds at rest and treat them with the respect that a United States war veteran deserves. In this case, it means answering as best we can the question of what is the result of dioxin exposure and determining what degree of government assistance is appropriate.

That is what we set out to do in 1979 when we passed P.L. 96-151 and that is what I would urge us to continue to do.

I have several questions to address to the Administration which I hope will come out during the course of today's hearing. In the event, they do not

come up, I have listed them below and request that a formal response be included in the record.

1) What is the cost of the CDC studies to date--this includes a breakdown of the costs of the individual studies?

2) What is the estimated total cost of the individual studies?

3) What other dioxin related research is CDC performing?

4) How does this other research relate to the Agent Orange study?

5) Are Agent Orange funds being used to develop research in other areas of the CDC?

6) What are the critical factors for evaluating the validity of the Agent Orange Study?

7) Do you believe that a study can be designed to meet these criteria?

8) If it wasn't possible to design a reliable study, would you recommend scrapping it?

7) If an alternative protocol is recommended using unproven tests, how can we be sure it is reliable?

8) What was CDC's role in the Times Beach, Missouri evacuation?

9) How does that action relate to the Agent Orange problem?

Lastly, Mr. Chairman, I would like to submit the testimony of the Agent Orange Committee of the Washington Stae Council of the Vietnam Veterans of America and request that the concerns they express be addressed by the Administration and included in the record.

In closing Mr. Chairman, let me again thank you, Rep. Daschle, and your staffs for their assistance in the past and for this opportunity to testify today. This is clearly one of our most difficult issues in Congress and I hope that today's hearing will remind all of those in government connected with the Agent Orange problem that our primary responsibility is to help those suffering in uncertainty.

United States of America,
House of Representatives
House Oversight Committee,
The Agent Orange Projects
July 31, 1986

The Honorable, Bob Edgar
Tom Daschle

Re: Written testimony, Joseph C. Cole

Washington State Council
Vietnam Veterans of America
Agent Orange Committee
Joe Cole/Chairman

Item # 1
(PROTOCOL)

Public Law 96-151, enacted in 1979, specified a protocol, which would withstand " scientific and peer review." In a letter, dated January 10, 1986, the Honorable G.V. (Sonny) Montgomery, Chairman U.S. House Veterans Affairs Committee, notified the Honorable Otis R. Bowen, M.D., Secretary U.S. Department of Health and Human Services, (C.D.C.) " No amendment, however, changed the requirement in P.L. 96-151 that the study shall be conducted in accordance with a protocol approved by the Director of the Office of Technology Assessment."

This letter, was the result of a complaint filed by Dr. John H. Gibbons, Director of the Office of Technology Assessment, December 19, 1985. In sum, the recent reports from C.D.C. outline an Agent Orange study of " radically different design than the one that was initially reviewed and approved by O.T.A. The changes in design are of sufficient magnitude to require interruption of any plans for initiating interviews or examinations of study subjects."

In the January 10, 1986, letter from G.V. Montgomery, to Dr. Bowen, the studies were halted. " In accordance with the law, no new major phase of the study, including contacting or examining study subjects, should be undertaken until the basic requirement of approval by O.T.A. is met. Specifically, we expect the C.D.C. to describe its intended design and protocol for the Agent Orange study in sufficient detail to permit a review by the O.T.A."

Further, " expenditure of funds for any purpose other than to prepare the appropriate documentation for review should be suspended pending that review."

In a September 1985, report, issued by, Robert C. Diefenbach, Public Health Advisor, Agent Orange Projects, Division of Chronic Disease Control Center for Environmental Health, (C.D.C.) the following statement is made; " Between August 1965, and February 1971, approximately 11.3 million gallons of the herbicide Agent Orange were sprayed over much of South Vietnam, in military operations designed to deprive the enemy of cover and food." Further, " in January 1983, the responsibility for designing and conducting the investigation was transferred from the V.A. to the Center's for Disease Control (C.D.C.). In May 1983, C.D.C. scientists completed detailed guidelines (Protocols) for the Agent Orange and Vietnam Experience studies, recommending that a third investigation be conducted at the same time to determine the risk of Vietnam veterans developing selected types of cancers." Public " Notice of Research Project Initiation " was published in the Federal Register on March 13, 1984.

On July 8, 1986, Congressman Bonker, recieved a letter from the Honorable, Thomas K. Turnage, Administrator, The Veterans Administration, with an enclosure indicating, " in 1983, the responsibility for the conduct of this study was transferred to the Center's for Disease Control.

I personally find this all very confusing. The V.A. and C.D.C, both appear to believe as stated, that the C.D.C. was in fact the authorized agency, in charge of the Agent Orange Projects. However, in a letter from Dr. James Mason, C.D.C., January 6, 1986, the C.D.C. expected to submit documentation for the design of the Agent Orange study in time for a March-April review by the Congressional Office of Technology Assessment (O.T.A.). What happened to the " May 1983, C.D.C. scientists completed detailed guidelines (Protocols) for the Agent Orange Vietnam Experience study." ?

Since " Operation Hades ", started sometime in 1962, using Agents known as (Pink, Green and Purple) and known to be contaminated some

twenty to thirty times greater, with the dioxin contaminent 2,3,7,8, T.C.D.D., Why then, is this study overlooking three of the potentially most harmful years of evidence ?

On October 24, 1984, Congress enacted P.L. 98-542, directing the V.A. to esfablish guidelines for the adjudication of compensation claims, based upon disabilities or deaths of certain veterans who, while in military service, were exposed to ionizing radiation or herbicides containing dioxin. What does this have to do with protocol you ask ? Section 1.17 Study evaluations. The body of commenter's, are attempting to use P.L. 98-542 as a control vechicle to dictate protocol definitions. i.e. " The commenter further recommended that the V.A. use such risk assessment principles rather than establishment of cause and effect in determining the relation between exposure to dioxin and diseases. The concept of risk assessment does not intrinsically differ from a cause-and-effect analysis." The Environmental Hazards Committee recommended that the words " Statistically and Epidemiologically valid " be substituted for the words " Statistically Significant." The committee noted that a study may present statistically significant findings and still not be a valid study.

Humans, not living in a test tube environment, make it impossible for a " cause-and-effect " relationship to ever be found, in this test or any other. In 1983, the C.D.C., informed the Office of Technology Assessment, that many of the proposed procedures are untested, modification, indeed even a recommendation not to proceed with an Agent Orange study, may be required after pilot study assessments. This statement, is obviously a contradiction of the mandate of Congress, and P.L. 96-151. I believe, that it also shows a knowledge of the C.D.C., that in all probability, the Agent Orange Projects, had very little chance of succeeding, under their design protocol, approved by the O.T.A., in 1983. I would further submit, that under a cause-and-effect proposal, they knew, there would be no chance of success.

Item # 2
World Literature, conflicting studies and reports. Policies of the U.S. Government.

The United States Department of Justice, The United States Environmental Protection Agency, The United States Food & Drug Administration, The United States Public Health Service, The United States Air Force and others etc., have all published reports, or been up-held in the courts of the United States, for presenting supporting evidence to the known health effects of toxic chemicals. While these reports do not specifically deal with Vietnam, the toxic chemicals in question are no less relevant. Thirtyfour million dollars, were spent for the purchase of Times Beach, Missouri. Recognizing the E.P.A. and government position, of this being a precautionary measure, the need for the precaution, comes from documented, verifiable research procedures. Many of these procedures have been either, repeated or originated other countries and are recognized as providing evidence of a relationship, between illness and exposure in humans. i.e. Sweden, Japan, West Germany, etc.

There have been numerous " Out of Court " settlements, which, while perhaps no finding of wrong doing can be indicated, one must examine the nature of the illness', types of chemicals, and the amount of the awards being paid, to " protect trade secrets ." While, I agree this amounts to being " circumstancial evidence ", Henry David Thoreau, perhaps said it best in 1850. (Some circumstancial evidence is very strong, as when you find a Trout in the milk.)

The protocol guidelines ordered by P.L. 96-151, would appear to require a study acknowledging World Literature statistics as well as any new data in the final decision making process.

Item # 3
Epidemiological Studies, statistical significance;

P.L. 98-542, enacted September 25, 1985, casts doubt on the definition of what constitutes an epidemiological study and the validity of statistically significant findings. Further, the law appears to indicate, that the Congress, is seeking a cause-and-effect relationship, using a epidemiological process. ..

P.L. 96-151, required a protocol, designed, and documented, which would withstand scientific and peer review. Seven years into the study process, definitions should have been well defined and not be in question. Guidelines, should have defined in the very begining, what would be considered as a statistically significant finding. These guidelines should be established, published and distributed, prior to the implementation of any further portions of the Agent Orange study, if any. One could only speculate, as to the intent of P.L. 98-542, in defining as intrinsically the same as cause-and-effect, but, I believe, as do many others, that epidemiological studies, relies on a finding of reasonable doubt, statistically significant, a probable reaction to a past exposure or event. Not 100%, but 51%, would be of significant importance. P.L. 98-542, gives the veteran that particular clause, in section 3.102, Reasonable Doubt. Where a reasonable doubt exists, doubt is ruled in favor of the veteran.

Item # 4
Establishment of reasonable time periods;

Seven years after enactment of P.L. 96-151, we're holding Oversight Hearings, to determine whether or not we can proceed with the Agent Orange Projects. Do we have an acceptable protocol ? Are all the definitions defined ? Are the management problems resolved ? Are we looking for statistically significant findings, or cause-and-effect relationships ? Will we use established procedures and methods, or continue with untested procedures and methods ? Will we have enough money, to continue to a satisfactory conclusion if we continue our research program ?

World Literature, has established, that some illness' suffered by Vietnam veterans, can be reasonably related to toxic chemical exposure. Congress, previously also recognized this possibility, with respect to three illness', (Chloracne, Porphyria Cutanea Tarda and Soft Tissue Sarcoma.)

I would propose, that in the interim, all veterans, whom currently suffer from these illness' (Vietnam veterans) be treated and compensated, while the final results of the study are being compiled and evaluated.

Further, in a letter to Congressman Bonker, The Honorable Thomas K. Turnage, Administrator, Veterans Administration, reported, that the V.A. has treated 1,376,000 Vietnam veterans for illness' they believed were related to their exposure to toxic chemicals, as ordered by P.L. 97-72. I would further propose, that the V.A. continue to treat those veterans, until such time as the final results of the Agent Orange Projects are completed. Compensation or denial of further treatment can be fully assessed at the time of completion of the studies.

These courses of action, I believe can be justified, by the current state of the Agent Orange Projects and the obvious breaches of Public Laws. Reasonable doubt is also quite evident in World Literature, as well as in the reports of many U.S. Government agency's.

Item # 5
Vietnam Veterans Committee;

As a member of the Vietnam Veterans of America, I am aware of the existence of a committee, in place, to work with the agency's involved with the Agent Orange Projects. The reason I have listed this in my testimony, is the current committee, for whatever reason, has been ineffective at carrying out their assigned task. The current state of the project, and the problems we are addressing in the Oversight Hearings, should provide ample documentation of this as fact.

Item # 6
Exposure index;

It has been scientifically established and accepted, that T.C.D.D. 2,3,7,8, dioxin, will bio-accumulate and that while technically dioxin is said to breakdown with time, the actual breakdown, only means, that the chlorines seperate from the dioxin.

Immune systems, like humans, are all different. Exposure to toxic chemicals and a diagnosis of that relationship to an illness, must also recognize a reasonable Exposure/Diagnosis timeframe. Specific illness' also require different incubation periods. Current V.A. guidelines on these issues, do not meet with realistic requirements for the illness' involved or the known chemical exposure dianosis time frames.

Dr. John H. Gibbons, expressed concerns of the C.D.C., with regard to the U.S. Army Environmental Support Group, and the problems of cooperation between the two agency's. The function of the E.S.G., was to as accurately as possible, determine the whereabouts and potential for exposure to toxic chemicals, of the individuals selected for the study group.

I find it very troublesome, that the Oversight Hearings, will not be attended by the E.S.G., since they are deeply involved in the current status of the project and apparently any continuation of the study. In P.L. 98-542, enacted September 25, 1985, a veteran whom served in Vietnam, is presumed to have been exposed to toxic chemicals. Recognizing the need for determining as accurately as possible, a persons exposure to chemicals, such as dioxin, for research purposes as important and valid, I only stress, that we not forget, the bio-accumulative effects and ability of dioxin or other toxins. Study subjects, might even more accurately be found amongst the civilian population. i.e. Times Beach, Love Canal, Woburn, Mass., Five Rivers, Oregon, etc. Keeping in mind, the amount of exposure in Vietnam, is listed at twenty times greater, than those used domestically.

Animal studies, throughout history, have been used as a reliable guide for humans. When all else fails, we should not allow the cost or potential cost of an issue, to overshadow the lessons learned by the established animal research studies.

Item # 7
Long Term Health Effects;

As previously noted, immune systems like humans are different, from one individual to the next. Long term effects are not now known, nor are they likely to be, in the lifetimes of the veterans exposed or currently being studied. These guidelines, must be established, using the only method currently available. Compassion, based on the current available data. If it is possible, within the perammeters of reasonable doubt, it should be recognized.

The Honorable, Don Bonker, Tom Daschle, Bob Edgar & G.V. Montgomery
The Agent Orange Projects/House Oversight Hearings
Page eight
July 21, 1986

Respectfully submitted for;

The permanent record of the House Oversight Hearings,
Epidemiological Studies of the Health Effects of Vietnam veterans,
The Agent Orange Projects/July 30, 1986
The Honorable, Tom Daschle and Bob Edgar, presiding

Sincerely yours,

Joe Cole
Washington State Council
Vietnam Veterans of America
Agent Orange Committee
1401 Foxfire Dr. S.E.
Olympia, Washington 98503

I Joseph C. Cole, Chairman, Washington State Council, Vietnam Veterans of America, Agent Orange Committee, do hereby swear, the preceding statement to be true and correct as documentation presents.

STATEMENT OF REP. TIM WIRTH

SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE

JULY 31, 1986

Mr. Chairman, I'd like to thank you for holding today's hearing to address the Administration's apparent failure to conduct a thorough study of Agent Orange. Vietnam veterans are deeply concerned about the impact of this toxic defoliant on their health. They deserve an aggressive federal inquiry into this matter, and I'm hopeful that our work here will ensure that they get such an inquiry.

Mr. Chairman, I understand that the Administration will soon declare the Agent Orange study scientifically unworkable. Despite six years of hard work on this study, despite the spending millions of dollars, the Administration is ready to just walk away from this critical effort.

In my view, this abdication of responsibility is flat wrong. Millions of gallons of Agent Orange were sprayed throughout Vietnam. Thousands of our troops were exposed to the defoliant. And many of our Vietnam veterans may suffer from adverse effects related to the toxic chemicals in Agent Orange. From my reading of the facts, there is no doubt that it is the federal government's job to determine the impact of Agent Orange on the health of Vietnam veterans.

That was why, seven years ago, I strongly supported the legislation, authored by Chairman Edgar and Mr. Daschle, which mandated the study of Agent Orange's health effects -- the very study we are debating here today. The Centers for Disease Control (CDC) were assigned to coordinate the inquiry, following the submission by the Office of Technology Assessment (OTA) of a design for the study.

At first, OTA developed a plan of study, which was of high scientific caliber. Unfortunately, CDC chose to modify -- quite substantially -- that plan. Dr. John Gibbons, Director at OTA, told the House Veterans Committee that "recent reports from CDC outline an

Agent Orange study of radically different design than the one that was initially reviewed and approved by OTA." He also informed the Committee that CDC was not providing enough written information to review this new design, especially the exposure assessment. In short, Dr. Gibbons told us that CDC is dramatically changing the ground rules for the study, a move that has slowed the study's progress to a crawl.

The dispute between CDC and OTA is not the only turf battle undermining this study. The Army's Environmental Support Group (ESG) -- which must provide the records and expertise to develop the study's data base -- is feuding with CDC over assembly of the data. Staff of the OTA and the House and Senate Veterans Committees indicate that the rift between CDC and ESG is extremely deep.

This is disturbing news, Mr. Chairman. The hopes of thousands of Vietnam veterans for an impartial, scientific study of Agent Orange should not be sacrificed because of bureaucratic battles.

Nor should they be sacrificed because the Administration and CDC argue that they cannot find an adequate test population of veterans for the study. The Administration points out that only 1,200 troops conducted the Agent Orange spraying operations. However, there is a reluctance to note the large number of troops that moved into defoliated areas before the threat of toxic contamination had subsided. For example, military records indicate that although troops were not supposed to enter a spray zone until 30 days had passed, they in fact occassionally entered such zones within a day of spraying. It should also be noted that the Army used Agent Orange to clear the perimeter of bases where troops were quartered on a long-term basis.

A careful review of the evidence, Mr. Chairman, indicates that there was ample opportunity for our troops in Vietnam to be exposed to Agent Orange spraying. It is hard to believe, given this potential for troops' exposure to the defoliant, that an adequate test population cannot be identified for examination.

The Administration's argument is a weak one, especially when we consider that 15 states

have begun inquiries into Agent Orange based on extensive surveys of affected veterans. Nothing more clearly illustrates the Administration's failure to confront the Agent Orange problem than this action by state governments across the country. Let me repeat: 15 states have felt compelled to launch their own examinations of Agent Orange.

The veterans in those states are fed up with the bureaucratic infighting and inadequate excuses which have held up the federal Agent Orange report for more than six years. They are tired of being told by the Administration that there is no correlation between the spraying of a dangerous defoliant -- containing dioxin -- and high incidences of birth defects, nervous disorders and other ailments. They appear to have lost faith in the federal government to address their legitimate concerns about Agent Orange, and have turned instead to the statehouses.

That, Mr. Chairman, is an unfortunate turn of events. Seven years ago, we took up the cause of veterans affected by Agent Orange. We promised a thorough study of the defoliant's impact on Vietnam veterans. Now the Administration appears ready to renege on that promise. It appears ready to turn its back on hundreds of thousands of Americans who served our country so unselfishly.

Approximately 150,000 veterans have claimed service-connected disabilities related to Agent Orange spraying. We owe those veterans a full accounting of the impact of Agent Orange on their health. We can do that if we renew our bipartisan effort to rise above the bureaucratic bickering and produce an impartial, scientifically sound study of that impact.

I am hopeful that we can use today's hearing as a means to knock the Administration out of its inertia -- to force it to recognize the seriousness of the problem -- to preserve the health and future of thousands of America's veterans.

We need forceful action now -- not further delay. And I am sure you will be among the initiators of that action, Mr. Chairman. You have my full support to see this study completed and I look forward to working with you.

FOR RELEASE ONLY UPON DELIVERY

Testimony of

James O. Mason, M.D., Dr.P.H.
Director, Centers for Disease Control
U.S. Public Health Service

DEPARTMENT OF HEALTH AND HUMAN SERVICES

before the

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON VETERANS AFFAIRS

SUBCOMMITTEE ON
HOSPITALS AND HEALTH CARE

Hon. Robert Edgar, Chairman

Thursday, July 31, 1986

9:00 a.m.

Room 334, Cannon House Office Building

INTRODUCTION

Good morning, Mr. Chairman, I am Dr. James O. Mason, Director, CDC. I am honored to be here to represent Secretary Bowen and Under Secretary Newman, who is Chairman of the Domestic Policy Council Agent Orange Working Group (AOWG). I welcome this opportunity to appear before the Subcommittee to describe the progress of studies of the health of Vietnam veterans being conducted by the Centers for Disease Control (CDC) especially the status of the Agent Orange Exposure study.

With me this morning are Mr. Ed Weiss who is here as acting Executive Secretary of the AOWG; Dr. Vernon Houk, Director of CDC's Center for Environmental Health; and Dr. Carl Keller, who has served as Chairman of the Agent Orange Science Panel.

BACKGROUND

Public Laws 96-151 and 97-72 directed the Veterans Administration (VA) to conduct investigations of Vietnam veterans' health. The first of these laws, signed in January 1979, dealt with the health effects of veterans' exposure to Agent Orange. The second, signed in November 1981, expanded the scope of the study to allow for the inclusion of other environmental hazards associated with service in Vietnam. CDC was assigned responsibility for design and conduct of the studies in January 1983 by an Interagency Agreement with the VA.

In May of 1983, CDC completed and submitted a draft research protocol for scientific review and comment by four groups: the Office of Technology Assessment (OTA), the Science Panel of the Agent Orange Working Group (AOWG), the HHS Advisory Committee on Special Studies Relating to the Possible Long Term Effects of Phenoxy Herbicides and Contaminants (the "Ranch Hand Panel"), and CDC's own independent Ad Hoc Review Panel.

The format for these studies was published in November 1983. It incorporated modifications suggested by the scientific reviewers and included three independent but related studies that together comprise the Agent Orange Projects. These studies are:

1) The Vietnam Experience: a study of the long-term health effects of military service in Vietnam, including reproductive effects.

2) The Agent Orange: a study of the long-term health effects of exposure to herbicides in Vietnam.

3) The Selected Cancers: a study to determine the risks of specific cancers among Vietnam veterans.

These three studies represent a comprehensive approach to evaluating the health of Vietnam veterans.

The Office of Management and Budget (OMB) gave preliminary approval for conduct of the studies in May 1984. By August CDC awarded the first of what would eventually be 15 major contracts for data collection. The first health interviews of Vietnam veterans --a test of systems to identify, locate, and collect data for the Vietnam Experience Study-- were begun in September 1984.

Data collection for the Vietnam Experience and the Selected Cancers studies were begun on the effective date of OMB's final approval in January 1985 and are continuing. Data collection for the Agent Orange exposure study was originally planned to begin in January 1986 but has been put on hold. I will briefly provide information on how the Vietnam Experience and the Selected Cancers studies are proceeding before reviewing the Agent Orange Exposure study in greater detail.

SEQUENCING OF STUDY COMPONENTS

Selection of veterans to participate in the Vietnam Experience study was begun first because identifying men for this study could be accomplished easily.

Further work was necessary to establish criteria with respect to herbicide exposure for the selection of participants in the Agent Orange exposure study. The Selected Cancers study follows a separate schedule which does not interact with the other two studies.

Data collection procedures for both the Vietnam Experience and Agent Orange exposure studies were designed to be used by the same competitively selected contractors. This approach was taken because it was less expensive and would ensure the integrity of the study design and uniformity of results. The contractors have recruited and trained professional staffs and purchased equipment to conduct extensive health interviews and medical, psychological, and laboratory examinations of participants. The contracts were based on the premise that, as the last of the interviews and examinations of Vietnam Experience study participants were being completed, the first Agent Orange exposure participants would have been identified. Thereby the interview and examination phases of both studies would continue essentially without interruption.

The delay in starting the Agent Orange exposure study has not had any direct effect on the Vietnam Experience and the Selected Cancers studies. Both have been proceeding on schedule.

STATUS OF THE SELECTED CANCERS STUDY

The Selected Cancers study will determine if Vietnam veterans are at increased risk of developing certain cancers which have been identified in the scientific literature as possibly associated with industrial or occupational exposure to phenoxy herbicides and their dioxin contaminant. The cancers are: lymphoma, soft tissue sarcoma, nasal and nasopharyngeal cancer, and primary liver cancer. This case-control study was proposed because the sample size of the two cohort studies is not large enough to provide answers about these relatively rare cancers. The cases are those reported from December 1984

through November 1988 to eight tumor registries. The controls are selected through a random digit dialing process. As cases and controls are identified, it is not known whether they are military veterans and, if they are veterans, whether they served in Vietnam.

Data for the Selected Cancers study will be collected from approximately 2000 cases and 1300 controls. As of June 30, 1986, data have been collected from 552 cases and 357 controls. The collection of data on new cases as they occur is proceeding on schedule and the ascertainment of new cases will continue until November 1988. Therefore, the conclusions of this study are planned to be published in 1989.

STATUS OF THE VIETNAM EXPERIENCE STUDY

The Vietnam Experience study was designed to evaluate possible health effects of the overall Vietnam "experience" by comparing the health status of a cohort of male U.S. Army veterans who served in Vietnam with a cohort of male U.S. Army Vietnam-era veterans who served elsewhere. This study examines a wide range of health outcomes (e.g., psychological, neurological, medical, etc.) and has three substudies: a mortality assessment, a health interview, and a medical examination. I will briefly describe the status of each of these.

Mortality Assessment

The Mortality Assessment study investigates the causes of death of 446 veterans who were among the 18,313 men selected as participants but were found to have died after leaving active military service. CDC has received and reviewed death certificates and other reports covering 437 (98 percent) of these deaths. The collection of these data was completed in April of this year. Analysis of these data is currently underway. A report of the findings from the Mortality Study is being peer reviewed and is expected to be published this fall.

Health Interviews

The first part of the data collection phase of the Vietnam Experience study --the health interviews-- has been completed on schedule, thanks to the exceptional cooperation of individual veterans and the support of veterans service organizations who have encouraged veterans to participate.

It was a challenge to locate the over 17,000 subjects from among the men CDC selected as candidates for the Vietnam Experience Study almost two decades after most had been discharged from the service. The CDC contractor responsible for tracing and interviewing veterans, Research Triangle Institute, Inc. (RTI) has been successful in tracing more than 92 percent of these veterans, and of the men contacted by RTI for interviews, 92 percent (15,310 veterans) have participated in the study. That is an exceptionally high participation rate.

Medical Examinations

A stratified random sample of 6,452 veterans who have been interviewed were selected for medical examinations and their names given to another contractor, the Lovelace Medical Foundation, Inc. Lovelace has contacted these men and asked each to undergo comprehensive physical and psychological examinations at their facility in Albuquerque, New Mexico. In participating a veteran agrees to interrupt his life for several days of travel, tests, and examinations. As of July 9, Lovelace had completed examinations of 4,048 veterans, and another 497 have been scheduled to be done between now and the end of September. Then this phase of data collection for the Vietnam Experience study will be completed.

The community of veterans has also been extremely cooperative during this more personally demanding medical examination phase. The more than 4,500 examinations already completed or scheduled represent just over 70 percent

participation by veterans contacted by Lovelace. Considering the investment in time and effort required by participating veterans, we think this is an excellent response.

One goal of this phase of the data collection process has been to ensure that the experience is as pleasant and "hassle free" as possible for the veterans. The contractor has asked each participant to evaluate every step of the examination process; from travel arrangements and hotel accommodations, to how they feel that they have been treated by medical and support staffs. The veterans' evaluations have been very positive: over 90 percent have rated the overall experience as "excellent." A member of the CDC Agent Orange Project staff is on permanent assignment in Albuquerque to work with the contractor.

Findings from the health interview and the medical examination will be published simultaneously and are currently planned for May 1987.

STATUS OF THE AGENT ORANGE EXPOSURE STUDY

The Agent Orange Exposure study was designed to evaluate possible health effects of exposure to Agent Orange herbicides by comparing the health of an exposed cohort of male U.S. Vietnam veterans with an unexposed cohort. The two cohorts should differ in their exposure to herbicides in Vietnam while all other health risk factors remain constant. Existing military records-- developed many years previously for military purposes-- are all there is available to separate individuals into a cohort who were most likely heavily exposed to these agents and into a cohort who were most likely to have been unexposed. In the original approved study protocol, numerous problems were identified regarding the categorization of veterans with respect to herbicide exposure. The protocol indicated that since the proposed categorization procedures were untested, verification through pilot testing would be needed before a final decision to proceed with the full scale study could be made.

The U.S. Army and Joint Services Environmental Support Group (ESG) has worked diligently and effectively in abstracting location data to identify potentially exposed and unexposed individuals for inclusion in the study. Using this information, CDC prepared and submitted to the Office of Technology Assessment (OTA), two reports on exposure assessment and for the Agent Orange Exposure study, one in February 1985 and another in November 1985. These reports indicated that it was possible to identify relatively few veterans with probable heavy exposure using information available to ESG. Initially, however, before the military records were evaluated, it had been anticipated that the difficulty would be in finding unexposed individuals. This exposure assessment problem led CDC to consider treating exposure as a continuous variable; however, this idea was rejected after review by the Agent Orange Working Group (AOWG) Science Panel and OTA. OTA recommended that the initiation of the Agent Orange Exposure study be delayed until a totally revised study protocol was developed and approved. The problem, however, is defining a reliable exposure index when data are not sufficiently detailed or nonexistent. CDC has revised the protocol with the exception of those portions relating to selecting the study cohorts.

Let me emphasize that the difficulties in assessing exposure are related to the scope and the content of the military records, not the manner in which these military records were abstracted by ESG. The records were designed for military purposes not for the purpose of doing epidemiologic studies. All available information from military records is being used and was abstracted appropriately by ESG.

Beginning in January 1984 and continuing until just weeks ago, an intensive effort to separate exposed from unexposed veterans has been underway by the ESG, the Science Panel of the AOWG, and CDC; the conclusion of this effort is that by using military records alone, it is not possible to distinguish between exposed and unexposed cohorts. Records indicate that only a small proportion of men in the seven pre-test battalions had a likelihood of

significant exposure to recorded Agent Orange sprays. A Subpanel of the Agent Orange Science Panel was established specifically to look at these issues. The recommendation of the Subpanel was that "Any study of ground troops which is dependent upon military records for the ascertainment of exposure to herbicides, not be conducted without an additional method to verify exposure." The basis for this recommendation was that the pilot study confirmed a potential for considerable misclassification of an individual's exposure to herbicides or dioxin as estimated from the military records alone.

Two issues were specifically confirmed by the pilot study as influencing the degree of misclassification.

- Unit dispersion - On a substantial number of days, personnel in combat units eligible for the study were not located together as a unit; rather they were dispersed geographically up to 20 kilometers that same day.

- Incomplete spray records - Expert opinion suggested that an unknown but apparently large proportion of fire-base perimeter spray operations were never recorded and the degree to which these unrecorded operations may have influenced exposure is unknown. The record of aerial sprays, i.e., the Ranch Hand missions on the so-called HERBS Tapes, are thought to be complete and without question.

CDC has suggested a method for verifying whether exposure to dioxin actually occurred in a cohort of Vietnam veterans classified as potentially exposed to Agent Orange by military records. This verification would compare the actual level of 2,3,7,8-tetrachlorodibenzodioxin (TCDD) found in veterans' fat or blood with the military record exposure estimate. Using these fat samples in conjunction with military records had been considered and rejected in 1983 during the development of the original protocol because of these factors:

- At that time it was believed that the half life of residual dioxin in previous exposed persons was too short (about 1 year) to be of use in a study done 15 or 20 years after exposure.

- The estimation of body burdens would require the use of fatty tissue for analysis. Twenty grams of fat, or a specimen about the size of a man's thumb, were required. It was not felt feasible to use this procedure in a large number of veterans because a surgical procedure was required.

Recent evidence indicates a much longer half life of dioxin in man. It is now known to be more than 5 years, so a study done 15 years after exposure (2-3 half lives) would still be able to detect residual dioxin in those who had been highly exposed. In addition, recent advances in technology indicate that it may now be possible to measure TCDD levels in blood rather than fat. CDC has been independently evaluating a method for measuring TCDD levels in blood. This evaluation will correlate TCDD levels in fatty tissue and in blood in individuals with little or no exposure and those with high levels of exposure to TCDD. The evaluation of the blood/fat level relationship will be completed and peer reviewed by September. If there is a correlation in this relationship, it may be possible to conduct a validation study to determine whether military records can be used to produce the two cohorts necessary for a scientifically sound Agent Orange Exposure study. Again, if the correlation is positive, CDC and ESG will develop a protocol for this validation. It is expected that the protocol, its review and final action by AOWG and OTA, will be completed by the end of this year.

If the validation study indicates that it is scientifically possible to separate exposed from unexposed veterans, then the method for identification of the two cohorts will be included in the Agent Orange Exposure study protocol to be evaluated by OTA and AOWG. An Agent Orange exposure study cannot be done if the validation study demonstrates that it is not possible to use military records to identify exposed from unexposed veterans.

The budget is the final area I will address. The total in-house costs for FY 1983-1986 for personnel, equipment, etc. are approximately $11.5 million which have been allocated across the three studies. This figure is an estimate since FY 1986 is not yet complete. The contractual costs/obligations are broken down by the specific study. The vast majority of the contractual obligations were made in FY 1984 when the funds were made available. For the Selected Cancers Study, the total contractual obligations to date are approximately $4.3 million; the Vietnam Experience study contractual obligations are approximately $17.3 million; and the contractual obligations for the Agent Orange Exposure study are about $26.0 million. These funds for the Agent Orange Exposure study have not yet been spent since this component has not yet started. In addition to these costs/obligations, it will be necessary to pay the contractors about $2.0 million for costs associated with keeping the Agent Orange Exposure study on hold through September. It will be necessary to negotiate final settlement costs with the contractors if this study cannot be conducted. All the funds have been provided by the Veterans Administration.

In concluding the summary of CDC's studies, the Vietnam Experience and the Selected Cancer studies are proceeding well and on schedule. The Agent Orange Exposure study's difficulties are due to inability to document exposure from existing military records. Verification of the exposure assessment by blood analysis may make it possible to do a scientifically valid study.

In addition to the ongoing work by the Centers for Disease Control, I should mention that this Administration has committed resources for over ten Federal agencies in addressing health issues of concern to Vietnam veterans. For example, the Veterans Administration has two studies about to be released (their mortality study and their soft tissue sarcoma study) and the U.S. Air Force has just completed another round of physical examinations as part of their continuing Ranch Hand Study. The combined efforts of these agencies under the guidance of AOWG represent an extensive commitment to resolving the health concerns of Vietnam veterans.

OPENING STATEMENT OF CONGRESSMAN TOM DASCHLE

Before the Subcommittee on Hospitals and Health Care
Committee on Veterans Affairs
July 31, 1986

I want to join Congressman Edgar in welcoming you all here today. It is especially good to see so many veterans here, since the destiny of this study is of ultimate concern to veterans.

I view this hearing as an important step in the decision-making process on the future of the Agent Orange study and am, thus, looking forward to hearing from those responsible for conducting that study. I am concerned, however, by the absence of key policy makers from the Administration who have been and still are involved in this effort.

For quite some time, some have speculated that the Administration has been less than forthcoming about the progress and future of the study. The hearing today was an opportunity for the Administration to calm those fears.

I want to commend the Chairman of the full Committee, Mr. Montgomery, and the ranking minority member, Mr. Hammerschmidt, and the Committee staff for their diligent efforts to gather information about the status of the study and their willingness to work out any problems that might exist. They have been monitoring this situation closely since the summer of 1985, when it became evident that the study faced major problems.

When the Agent Orange study was suspended due to problems in determining an acceptable methodology to assess exposure, the Science Panel of the President's Agent Orange Working Group was asked to evaluate the possibilities for exposure assessment and to conduct a pilot study based on these findings. The Panel completed these tasks on May 28 and has reported its findings to the Agent Orange Working Group. Until now, we have been unable to obtain the results of their work.

Congress is faced with important policy decisions regarding this study and our treatment of veterans who served this country in Vietnam, and I cannot think of a valid reason for the Administration to withhold this information.

The Agent Orange study is at a major crossroads. Congress first authorized this study in 1979. Now, seven years and millions of dollars later, Congress and Vietnam veterans are still without an approved protocol for the study. Congress has a right and an obligation to assess the progress and merits of the study, and after numerous unexplained delays and unanswered questions, we are anxious to hear what you have to say.

TESTIMONY BY MR. RICHARD S. CHRISTIAN

DIRECTOR

U.S. ARMY AND JOINT SERVICES

ENVIRONMENTAL SUPPORT GROUP

BEFORE THE

SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE

COMMITTEE ON VETERANS' AFFAIRS

of the

HOUSE OF REPRESENTATIVES

July 31, 1986

Not for Publication until Released by the Hospitals and Health Care Subcommittee, House of Representatives

Statement Record Version

Mr. Chairman and Members of the Committee:

I am Richard S. Christian, Director of the U.S. Army and Joint Services Environmental Support Group (ESG), Department of the Army. I am pleased to appear before the Committee to provide, in response to your request, ESG's research missions in support of the Agent Orange Epidemiological Study, mandated by Public Law 96-151.

The Army became actively involved in the Agent Orange issue early on because we recognized its importance to operational readiness.

As the major Service involved in the subject, the Army is The Executive Agent for all the Services on this issue.

Two point four (2.4) million Americans served in Vietnam from 1961 to 1973. These men and women served their country admirably. They deserve our care.

The Army is keenly aware of its obligation and is dedicated to help Vietnam veterans. The American Soldier, Sailor, Airman and Marine is intelligent and wants frank answers to his concerns, and that is ESG's purpose: to provide such answers.

In the last six years ESG has led in research, assistance, and providing information to Vietnam veterans.

Over 20,000 inquiries have been answered regarding veterans issues. Eighty-Five percent(85%) of these inquiries related to the issue of exposure to Agent Orange.

Mr. Chairman I will outline the record of ESG involvement in various Agent Orange studies.

First I must state the obvious in order to avoid the hope of easy answers. Unfortunately, but not unpredictably, combat operations were not designed as an epidemiological laboratory. Combat does not contribute to anyone's health, nor does it favor scientific review that is based on the correlation of statistics. Yet, the records generated during military conflicts can serve many uses. I will briefly describe our efforts in reviewing the records from Vietnam.

Our first study involved Birth Defects. In December of 1983 ESG provided the Centers for Disease Control (CDC) exposure opportunity scores on 536 Vietnam veterans. This required ESG to develop a procedure to identify a unit's area of operation for each participant in the study. In addition, ESG established a board of military experts to evaluate each case.

Another phase of ESG operations involved assistance to veterans and the Department of Justice. Hundreds of documents were provided in connection with the civil class action lawsuit involving the Vietnam veterans, chemical companies and the U.S. Government. The claim against the U.S. Government was later dismissed, except for wives and dependents claims. This was a major undertaking, as our job involved records support for all parties. It meant examining and cataloging the 40,000 linear feet of combat unit records from the Vietnam conflict.

ESG provided additional exposure opportunity scores on Vietnam veterans for the Veteran Administration's Chloracne and Adipose Tissue Studies.

We are currently doing military research on eight other VA studies concerning Agent Orange.

As to the current interaction with the CDC, CDC was provided personnel data for over 20,000 study subjects for what is termed the Vietnam

Experience Study. This study covers all those factors, including Agent Orange that may have contributed to potential ill health of the military personnel who served in Vietnam. Despite the requirements of abstracting 73 personnel data elements for each study subject, this task was completed ahead of schedule. To supply this information 43,000 personnel files had to be analyzed.

In 1983, the Science Panel and Office of Technology Assessment approved ESG's portion of the Agent Orange Epidemiological Study protocol.

On 1 April 1984, we began the research for both the Vietnam Experience Study and the major Agent Orange Study.

Changes were frequently made in battalion tracking for the Agent Orange Epidemiological Study and personnel data abstraction, for both the Agent Orange and the Vietnam Experience Study. This required frequent adjustment of research to add, check, refine, assess and massage the data.

In July 1984, we were informed that eleven CDC contracts were signed, resulting in new time tables for ESG. We adjusted to meet the new deadlines. Time tables and numbers of subjects and disqualification factors repeatedly changed over the ensuing months.

In November 1984, a major change in workload required ESG to research an additional 15 battalions, and revise the selection process for Agent Orange study subjects. Concurrently for both the Agent Orange and the Vietnam Experience Studies, CDC requested more documents for deceased veterans.

In January 1985, CDC assigned new time frame deadlines and again increased the amounts of personnel data required.

Differences in quality control between the military and the investigators occurred. Nonetheless, these issues were resolved after mutual education of the scientists and military experts in military operations,

language, procedures and scientific techniques.

Due to lack of agreement on assumptions, government scientists never approved an exposure model crucial to the study.

On September 12, 1985, ESG completed the only record of documented military spraying by helicopter, backpack, ground spraying, aborts and leaks. This document, now known as the "Services Herbs Tape," provided a second source, other than the Air Force Operation Ranch Hand, for the matching of units to Agent Orange spraying.

Defoliation spraying may have occurred at main base camps, fire support bases and landing zones. Unfortunately, the records are not complete enough to substantiate the magnitude of these operations. Whether or not these bases were sprayed by Orange, Blue, White or diesel fuel is not known to us since complete documents are not contained in the units' records. In the 9th Infantry Division's area alone there were about 365 such locations that might or might not have been sprayed. Yet, the records only show a total of 478 perimeter sprays for all of Vietnam during the entire war, although there were 11 plus U.S. Divisions, 2 Korean Divisions, 1 Thai and 1 Australian Division in Vietnam.

The Chairman of the Science Panel, Agent Orange Working Group then tasked ESG to conduct a decisive Pilot Study on unit/troop exposure.

Accordingly, ESG researched and completed grid coordinate locations for all companies of seven combat battalions covering the period 1 October 1966 to 31 March 1969. ESG then matched the grid coordinate locations of each company by date against the Ranch Hand and "Services Herbs Tape" to produce an exposure opportunity score for each company. ESG then provided unit exposure opportunity scores on 700 individuals from these units using varying time and distance criteria.

The Pilot Study results revealed the dispersion of combat companies on one-half the given days and that the units had little contact with Agent Orange herbicide spray missions.

These were startling discoveries by even my own staff and the White House Agent Orange Working Group Science Sub Panel, charged with evaluating all available data. We had anticipated higher numbers of exposure than what were actually recorded.

It should be clearly understood that ESG can identify a combat company's locations on a given day. However, records do not permit the location of individual sub-elements or individual troops within these sub-elements at each location. ESG is not qualified to answer the scientific problems this creates. This is an issue the scientists must address. ESG can only report what is contained in the records.

The Military Services performed all this work without outside funding. Over the past six years we have expended 6 million dollars for these efforts.

In summary: over the past three years the Military Services have been scrutinized, scrubbed and critically examined by distinguished groups of experts, such as the National Academy of Science, The Science Panel of the White House Agent Orange Working Group and most recently the Science Subpanel on Agent Orange assessment. The records do not support continuance of the Agent Orange Epidemiological Study, that is, a study based solely upon the use of military records to select cohorts on men potentially exposed to Agent Orange. We are proud of our exhaustive work.

I shall be most pleased to answer any questions.

TESTIMONY OF HELLEN GELBAND
OFFICE OF TECHNOLOGY ASSESSMENT
U.S. CONGRESS
BEFORE THE SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE
OF THE HOUSE COMMITTEE ON VETERANS' AFFAIRS

Review of OTA Activities Related to Exposure Assessment for the Agent Orange Study

July 31, 1986

I am Hellen Gelband, Director of Special Projects and Agent Orange Project Director in the Health Program of the Office of Technology Assessment. OTA was given responsibility for reviewing and approving study protocols, and monitoring the conduct of studies, under the mandates of Public Laws 96-151 and 97-72. I'd like to relate briefly OTA's involvement specifically related to Agent Orange exposure assessment in one of the three studies planned by the Centers for Disease Control in response to Congress's mandates. I will not chronicle the history of the study before the time CDC gained responsibility for it.

The Agent Orange study was proposed to examine the question of whether ground troops exposed to Agent Orange in Vietnam are more likely to be dying at a faster rate or are in poorer health than are similar men who served in Vietnam but were not exposed to Agent Orange. The study hinges on an ability to assemble groups of men that are different with respect to exposure, but similar in as many other ways as possible. This difference may be expressed in several ways: high and low levels of "exposure opportunity," and high and low "probabilities of exposure" are the types of terms applied. In the end, however, whatever names are used, it is critical that there be a high degree of certainty that the groups actually are different in their exposures to Agent Orange. That does not mean that every man in the high exposure group was actually highly exposed, or that each man in the high exposure group was exposed to more than any man in the low exposure group. It does mean, however, that the groups should be clearly different and that we should be able to characterize, at least roughly, what the difference is in logical terms. Today, seven years after the Agent Orange study

was mandated, after much effort, there is still no clear answer about whether groups of ground troops that differ in their exposure to Agent Orange can be identified.

From the outset, in the protocol outline produced in February 1983, CDC recognized the difficulties of obtaining good information about Agent Orange exposure. The feasibility of using military records that contained information about troop movements together with other records that contain Agent Orange spray locations had been shown in 1979 by the General Accounting Office, and it is that strategy that has been the focus of CDC's attempts to devise a scheme for exposure assessment. The intent was always to select study participants on some records-based measure of proximity in time and space to Agent Orange applications.

In June 1983, OTA reviewed protocols for the three studies planned by CDC, one of which is the Agent Orange study. Because of the great uncertainties concerning the records--particularly how complete they were and how accurate they were considered to be--no final decisions could be made about the study as a whole. As OTA stated in its review of that document, "it is still possible that studying associations between health effects and Agent Orange exposure may not be possible because the records will not provide information for meaningful exposure classification." In their revised protocol, which OTA received in January 1984, CDC stated: "Since many of the proposed procedures are untested, modification, indeed even a recommendation not to proceed with an Agent Orange study, may be required after pilot study assessments." In February 1984, OTA approved the general structure of CDC's revised protocols, while noting that the details of a method for classifying men according to Agent Orange exposure had yet to be worked out. As CDC stated in their document, final decisions about the feasibility of the study would have to await results of pilot studies of the methods and consideration of their results. OTA agreed that this was an appropriate way to proceed.

The general approach outlined by CDC was to select 50

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battalions from a heavily sprayed area during a time of heavy Agent Orange use, and rank each company (about 250 companies in total) according to a cumulative Agent Orange exposure "score" based on some combination of time and distance measures. The area chosen was the area designated "III Corps" during the period 1967 through 1968. The one-third of companies with the greatest opportunities for exposure would supply the exposed group, and the one-third with the fewest opportunities would supply the unexposed group. OTA believed at the time that CDC needed to set the requirements for the necessary records research and pilot tests so they could be implemented by the U.S Army and Joint Services Environmental Support Group.

CDC transmitted its first report about exposure assessment to OTA in February 1985, two years after CDC took control of the study. At that time, data from battalion daily journals, the main source of grid coordinates for companies and battalions, were available for 21 battalions for the two-year period. Because grid coordinates were not recorded each day for each company, gaps existed. CDC described two types of information that could be used to fill gaps: battalion and brigade-level records that might contain additional grid coordinates, and geographic names or name codes that appeared in some records in lieu of grid coordinates for unit locations. Many of the place names could be located at specific grid coordinates by use of a gazeteer. ESG used these additional sources of information to fill gaps, where possible, for nine of the 21 battalions whose records had been abstracted. According to the data presented by CDC in their report, even with the additional data, there were too many gaps for companies to be used as the unit for characterizing Agent Orange exposure. As stated by CDC:

> For these reasons battalions rather than companies or batteries will be the units whose locations form the basis for ranking individual men's likelihood of exposure to Agent Orange.

The shift from considering exposure based on a company to exposure based on battalion locations constituted a major change from the original protocol. The second major change presented in

the February 1985 report was that men would not be selected into the study by units, but by individual rankings. CDC reported that high transfer rates of men among battalions necessitated this change.

The OTA advisory panel met in February 1985 to review these changes, and OTA produced a report in April. The first change is of far greater importance than the second. A company contains about 100 to 150 men, while a battalion is five times as large, upwards of 500 men. Battalions are spread out over much larger areas than are the individual companies that make up the battalion. CDC presented data showing multiple reported locations for a single battalion on a single day. The different locations represent the positions of individual companies or other subunits of the battalion. Using those locations, CDC calculated a "centroid," an "average" point which was assigned, for the purposes of the study, as a uniform location of each man in the battalion. According to the data supplied in CDC's report, a reported location could be nearly 20 kilometers from the centroid, and in fact, there might not be one person actually at the centroid (see Figure). The degree of misclassification that would be introduced by this approach appeared extremely high.

To quote from OTA's April 1985 report:

> These are serious problems, but OTA comes to no conclusion about their impact on the study at this time. We expect to hold another meeting in about six months to hear from CDC about any improvements that can be made. If there are no improvements, OTA may decide that the problems of deciding on exposure are so overwhelming that it is impossible to study the possible effects of Agent Orange.

As a followup to our February panel meeting, OTA staff met with Mr. Richard Christian and his colleagues of the ESG to discuss the problems CDC had raised about the lack of information in the records for determining locations for companies. It appeared that, in fact, ESG was able to locate companies, if CDC would agree to using different types of information. OTA staff urged that CDC and ESG hold a meeting to discuss that question, which they did successfully, and ESG began to develop what has

been called the "contextual approach" to filling gaps in location data.

In late September 1985, Dr. Gibbons wrote to the Congressional committees, expressing concern that no new information about CDC's exposure assessment activities had come to OTA, but that CDC had not changed their plans for interviews of study participants to begin in January. Discussions between CDC and OTA resulted in CDC's agreeing to provide a revised plan for exposure assessment before the scheduled interviews. OTA received relevant documents between November 18 and December 13, and held an advisory panel meeting on December 14 to review the material with the hope that the plan would be far enough advanced to allow undertaking the interviews with confidence that the study would proceed on a sound footing. Unfortunately, what we found was to the contrary. Quoting from the letter sent by Dr. Gibbons (December 19) to the committees as a result of that meeting:

> In sum, the recent reports from CDC outline an Agent Orange Study of radically different design than the one that was initially reviewed and approved by OTA. The changes are of sufficient magnitude to require interruption of any plans for initiating interviews or examinations of study subjects.

CDC did finally have data on a company level and some on an individual level, but for no companies had all the gaps been filled, so the information was still incomplete. CDC did not comment on the unexpectedly low level of exposures seen in the data, and evinced no skepticism about the viability of the study. OTA did, however. The serious problems still existing led to OTA's recommendation that "no major new phase of the study should be undertaken before the new design and exposure assessment method are found acceptable."

Dr. James Mason, Director of CDC, wrote to the committees on January 6, 1986, responding to OTA's assertions. About exposure assessment, the letter states:

> We have a model for assessing exposure/nonexposure for persons selected...This is one of the most comprehensive models for possible exposure to an environmental contaminant thus far devised. What remains to be done is to develop methods of record

> reviews to locate as accurately as possible the placement of these men on each day they were in Vietnam.

The letter also stated that the design changes noted by OTA had been presented to the AOWG Science Panel and that the Science Panel "supported the design changes." It goes on to say, "We are currently preparing a more extensive statement, as requested by OTA, which we believe will clarify and substantiate the design change." The report was to be submitted to OTA "in time for a March-April 1986 review." The letter clearly states CDC's intent to proceed with the interviews as planned, continuing for at least three months, but stopping short of performing physical examinations, which would be scheduled for late May or June 1986. To quote, "It is at that point that the study can be aborted if available information is inadequate to distinguish between nonexposed and exposed Vietnam veterans."

Both the House and Senate Veterans' Affairs Committees responded to Dr. Mason's letter with letters to HHS Secretary Bowen (January 10, 1986) expressing their concerns about the study. Both letters stated that, by law, no new major phase of the study could go forward until a protocol, including a method of exposure assessment, was approved by OTA. The letter from the Senate stated that interviews should not be conducted until such time as a protocol was approved. While CDC based its decision to go ahead with interviews on fiscal considerations, the Congress voiced its concern about "the implications of interviewing subjects for the study only later to advise them that the study is not going forward." Such an action could be interpreted as an attempt to cover up early findings. To quote again, "Such a result would be particularly unfortunate and undesirable." In response to the Committees' letters, further interviewing was not carried out. We do not know how many interviews actually took place.

At the same time that letters were sent to Secretary Bowen, the Senate Committee wrote to the President, reminding him of his responsibility, as laid out in PL 96-151, of assuring that "studies of the Federal Government with respect to adverse health

effects in humans of exposure to dioxins are scientifically valid and conducted with efficiency and objectivity."

To date, OTA has not received a new protocol for the Agent Orange study from CDC. The major activity that we are aware of is the undertaking of the AOWG and ESG in assembling a set of complete location data for the study period for 7 combat battalions, and examining the potential use of the data, along with information about Agent Orange applications, to identify individuals with high and low probabilities of Agent Orange exposure. OTA was not directly involved in this activity, which was undertaken by a subpanel of the AOWG Science Panel, under the chairmanship of Dr. Young, the representative from the Office of Science and Technology Policy. The first official OTA involvement came at the time of the Science Panel review of the Subpanel report, in our role as observer. We have not received the report officially, and our advisory panel has not met to discuss it. I believe, also, that the report has not yet been made a public document. It is therefore inappropriate for me to comment on the substance or recommendations contained in that report.

OTA's most recent involvement came in the form of a June 26 letter from HHS Under Secretary Donald Newman, chair of the AOWG. That letter requested OTA's permission for CDC to prepare a protocol for a validation study to explore a possible correlation between dioxin in blood with a records-based definition of Agent Orange exposure. OTA Director Gibbons responded (July 11) by stating that "OTA's statutory role is limited to approving protocols and monitoring the conduct of studies" under the mandates of PL 96-151 and 97-72. OTA does not have the authority to grant such approval. To my knowledge, CDC has not been prohibited from preparing such protocols, only from embarking on the studies themselves without protocol approval.

Thank you for the opportunity to report on OTA's mandated activities related to exposure assessment for the Agent Orange study. I will be happy to answer any questions you may have.

QUESTIONS FOR THE HEARING RECORD
AGENT ORANGE HEARING--JULY 31, 1986
SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE
HOUSE COMMITTEE ON VETERANS' AFFAIRS

QUESTIONS OF SUBCOMMITTEE CHAIRMAN BOB EDGAR

E1. Question:
Two Committee letters have been sent to Secretary Bowen asking for the status of the Agent Orange study and a timetable for the steps remaining to get that study underway. Interim responses to these letters have been received. When can we expect the final responses?

Answer:
On August 11, Secretary Bowen wrote both House and Senate Veterans Affairs Committees advising them of the status of the Agent Orange study. An update providing information was transmitted to both Committees on September 8, 1986.

E2. Question:
In your testimony, you described the tasks of the Special Subpanel on Exposure Assessment of the Agent Orange Working Group. These are steps that would have been expected to have been previously performed by the Centers for Disease Control (CDC). What were CDC'S findings on these issues?

Answer:
CDC was aware of the issue related to the dispersion of troops within a combat unit. Data on this was provided to OTA in the February 1985 and November 1985 exposure assessment reports submitted by CDC. However, the finding (based on expert opinion) that an apparently large proportion of firebase perimeter spray operations were never recorded was information that had not been previously supplied to CDC.

E3. Question:
The latest interim response to our inquiries stated that the Secretary was awaiting the decision of the Agent Orange Working Group with regard to the Special Science Subpanel report. The work of the Subpanel was completed on May 28 and the Science Panel sent its comments on the report to the Working Group in mid-June. What is taking so long for the Working Group to act?

Answer:
The Subpanel report confirmed previous concerns that military records would not provide a scientifically reliable basis for selecting exposed and unexposed cohorts for an Epidemiological Study of the possible long term health effects of Agent Orange. The Subpanel report strongly recommended, and the Science Panel concurred, that an Agent Orange Epidemiological Study based on military records alone not be conducted without verification of exposure from an additional source. Since the Secretary of HHS had already ordered the Agent Orange Study to be halted, as requested by Congress in January of 1986, there was no further immediate action to be taken.

A method for verification of exposure has been proposed by the CDC, and is being pursued. This procedure consists of several phases, each of which must be completed and reviewed before proceeding with the next.

The first of these has been ongoing for several months and involves testing of a feasible method to determine human tissue levels of dioxin. Pending the successful outcome of this phase, a protocol is being developed for a study to compare tissue levels of veterans thought to be exposed and unexposed based on military records. These two tasks should be completed by early September 1986, and the protocol will be reviewed by the Agent Orange Working Group and the Office of Technology Assessment. Pending the outcome of this review, a verification study could begin shortly thereafter.

E4. Question:
I understand that the Special Subpanel on Exposure Assessment recommended that an Agent Orange study of ground troops which is dependent on military records for the assessment of exposure to herbicides, not be conducted without an additional method to verify exposure.

What is the confidence of your scientists that the additional method to verify exposure mentioned in your testimony would work?

Answer:
We have established that it is possible to measure dioxin in human blood. We will not know until we complete a validation study involving veterans whether or not it will be scientifically possible to separate exposed from unexposed veterans. Even then, it will be necessary for the U.S. Army and Joint Services Environmental Support Group (ESG) to determine if enough men can be found from the military records to carry out a full-scale Agent Orange Exposure Study.

5. Question:
a. In the first paragraph of page 9 of your testimony, you mention the "ongoing approved study protocol". When was that protocol approved?
b. Have you ever developed a protocol reflecting your revised methodology for determining exposure assessment and submitted it to OTA for review?
c. Why has it taken so long for CDC to recognize that their current exposure assessment methodology is not adequate and a different method to verify exposure is needed?

Answer:
a. The original approved protocol was reviewed during 1983, modified and then published in November 1983.
b. CDC has not submitted a revised methodology for exposure assessment to OTA for review. CDC did complete a draft revised protocol in February 1986; however, finalization of an exposure assessment methodology was dependent upon the findings of the Subpanel of the Agent Orange Working Group Science Panel. As a result of the findings of this Subpanel, CDC has proposed a validation study to try to determine if there is a method for identifying and separating exposed from unexposed veterans.

c. CDC's approach to exposure assessment has been based on the assumptions that individual veterans could be located on a daily basis (or on the vast majority of days) and the spray records (both the Herbs and Service Herbs tapes) were nearly complete. While CDC has been aware of the problem associated with dispersion of troops within combat units, the information (based on expert opinion) that an apparently large proportion of firebase perimeter sprays were never recorded has not been previously supplied to CDC. The problem is the lack of data to do a scientifically valid study, not necessarily a problem with the approach or method to use that data.

E6. Question:
In reality, it appears that a Subpanel of the Science Panel of the Working Group discovered the flaw in the proposed exposure assessment methodology, not CDC.

If a revised protocol reflecting the CDC's proposed exposure assessment had been drafted and submitted for the normal review and approval process, wouldn't this flaw have been discovered earlier?

Answer:
While there has been a lot of discussion about the best (or most appropriate) exposure assessment methodology, the findings of the Subpanel of the Agent Orange Working Group Science Panel related to incomplete spray records and lack of data on individual's locations, not flaws in exposure assessment methodology. This is a key point. The problem is the lack of data or lack of sufficiently detailed data to do a scientifically valid study.

In response to the second part of your question, the answer is this "flaw" might likely not necessarily have been discovered earlier even if a revised protocol had been submitted for review because the information regarding the completeness (or incompleteness) of perimeter spray records had not been provided to CDC. Therefore, magnitude of the problems with separating exposed from unexposed veterans was not known by CDC.

E7. Question:
In your letter to this Committee dated January 6, 1986, you said that CDC had "one of the most comprehensive models for possible exposure to an environmental contaminant thus far devised." Has that model ever been submitted to OTA as part of the Agent Orange Protocol?

Answer:
No it has not been submitted to OTA as part of the Agent Orange Protocol. It was, however, presented to the Agent Orange Working Group Science Panel and the Office of Technology assessment in CDC's November/December 1985 report on exposure assessment. Based on their review of that report and concerns regarding the exposure assessment methodology and analytic plans, OTA recommended a delay in the initiation of the Agent Orange Exposure Study.

QUESTIONS OF HONORABLE THOMAS A. DASCHLE

D1. Question:
a. CDC has proposed a new blood test for detecting the level of dioxin in the body. Since the scientific validity of the test is still to be determined, (1) I am interested in whether or not there are scientifically valid methods of tracing dioxin in the body already available to us? (2) How has dioxin been traced in the people involved in the Times Beach and Seveso accidents and in other studies? (3) Would any of these methods be useful to this study?
b. (Enviro-Health Systems, Inc., of Richardson, Texas, claims to have the approval of the U.S. Department of Health, under the Federal Clinical Laboratories Improvements Act, to conduct simple, inexpensive ($185 Per person) tests that trace levels of 2,4-D and 2,4,5-T in the body. (1) Is this true? (2) Are these tests applicable to this study? I have information on this lab if you need it.)

Answer:
a. (1) Current technology permits dioxin (specifically 2,3,7,8-TCDD) to be measured in about 5 grams of human adipose tissue. This allows for "tracing dioxin in the body." (2) This was the analytical technique used to monitor dioxin in individuals living in Missouri. (3) However, obtaining adipose tissue biopsies is an undesirable technique for any large scale epidemiologic study. As state-of-the-art technology has progressed in high resolution gas chromatography mass spectrometry (GCMS), it has been possible to detect 2,3,7,8-TCDD at lower and lower levels. The efforts at CDC have been to establish and validate a method for 2,3,7,8-TCDD in blood serum to allow the use of serum samples in epidemiological studies.
b. (1) Concerning Enviro-Health Systems, Inc., we are familiar with this laboratory. They are licensed through the Texas Department of Health and the National Health Care Finance Administration to test for 2,4-D, 2,4,5-T and related phenoxy acid herbicides in urine. Additionally, they are enrolled in the basic CDC Laboratory Proficiency Testing Program. However, the CDC program has been primarily directed toward clinical chemistry tests and has never included the analytes for which the Enviro-Health System, Inc., laboratory is licensed to measure. Therefore, no proficiency testing samples have been provided this laboratory from CDC or any other HHS agencies.

(2) Because of the relatively short half-life of 2,4-D and 2,4,5-T in the human body, tests for these analytes are not applicable to this study.

D2. Question:

a. What about the possible long.term effects of dioxin?

b. How does the new finding that the half-life of dioxin could be as long as ten years affect the study?

c. Also, since it has been more than ten years since veterans returned from Vietnam, what are (sic) the possibility that dioxin that could have been in the body and caused adverse effects but would now be untraceable?

Answer:

a. A wide variety of deleterious long-term effects of dioxin exposure have been suggested in medical literature. However, with the possible exception of chloracne, conclusive evidence that dioxin causes these effects in humans is lacking. Possible, but unproven, effects of dioxin include: cancer (soft-tissue sarcomas, lymphomas, hepatocellular carcinomas); birth defects; miscarriages and other reproductive effects; effects on metabolism (e.g. high triglyceride levels and a rare liver disorder called porphyria); neurologic and psychiatric effects (fatigue, loss of appetite, sexual dysfunction); and effects on the immune system (suppression). While each of these effects is suggested by one or more published reports, additional studies have failed to confirm these findings.

b. This new finding is important because it means that the dioxin levels of men who were exposed to dioxin during the Vietnam war might still be elevated and therefore detectable, even 15 to 20 years later.

c. Available data do not allow determination of the minimum level of dioxin which can cause health effects. Therefore, the possibility can not be dismissed entirely that exposure to Agent Orange (dioxin) during the war could have caused health effect, yet be undetectable now. Nevertheless, dioxin levels as a result of exposure which may have occurred at the time of the Vietnam war should be detectable in fat (and in serum if levels in fat and serum are reasonably related to one another) if the half-life is longer than five years. Therefore, documentation of health effects, or the absence thereof, in men who have elevated levels (provided such men can be found) should provide valid and useful evidence concerning dioxin's possible health effects.

D3. Question:

a. Do you think a valid study is possible?

b. If so, what needs to be done to facilitate that outcome?

c. If not what makes the study impossible?

Answer:

a. As stated in the testimony, because of the problems of using military records alone, we do not believe a scientifically valid Agent Orange study can be done if the validation study does not provide information which can be used to separate exposed from unexposed veterans.

b. Nothing beyond supporting the conduct of the validation study to determine if an Agent Orange Exposure Study is possible.

c. The major scientific problem is how to identify and separate exposed from unexposed veterans. If we do not have reliable information on the daily location of individuals and we do not have a complete record of all spray missions (in particular, firebase perimeter sprays), there exists the possibility for considerable misclassification of an individual's exposure status. That is, veterans who were really exposed might be categorized as unexposed and vice versa. Therefore, without a method to verify exposure, it would not be possible to conduct the Agent Orange Exposure Study.

D4. Question:
Dr. Houk stated that the Agent Orange study has had three different directors. My recollection is that there were five. Could you clarify this for us? I will ask that your answer be inserted at the appropriate point in the record.

Answer:
There have been three Project Directors, Dr. Erickson, Dr. Layde, and Dr. McGee. Mr. Scally is currently the Acting Project Director.

QUESTIONS OF HONORABLE THOMAS J. RIDGE

R1. Question:
Identify the criteria established by the CDC for the selection of participants with respect to herbicide exposure in the Agent Orange Exposure Study. If there is a document or memo identifying and explaining the criteria, a copy is requested.

Answer:
In the original approved protocol, CDC detailed a multi-step procedure to select veterans for the Agent Orange Study. A copy of protocol pages 10-15 (Attachment 1) which describe these procedures is attached to this document.

The basic approach was to choose a random sample of battalions stationed in the III Corps area of Vietnam during 1967-1968. If a battalion had more than 30 continuous days or 60 total days of absent records for the period 1967-1968, the battalion would not be used for the study. Individual company level units would be tracked on a daily basis and a score (for herbicide encounters) would be computed for each company. The companies would then be ranked by their score and individual men would be selected from the top and bottom one-third of the companies to maximize exposure separation. The individual men would then also be scored based on their daily locations and herbicide encounters. Individuals who were absent from their units for more than 90 days of their scheduled 12 month tours (exclusive of their regular R & R leave) would be considered ineligible for final selection. The rationale for this process is detailed in the attached pages 10-15 of the protocol.

There have been some changes made to these criteria in order to qualify more veterans than these original criteria would allow without jeopardizing the scientific design of the study. The basic problem, however, is that while a company's location on a given day can be identified, military records do not permit the location of individual sub-elements or individual troops at each location. Therefore, the exposure score of any individual veteran is subject to question.

R2. Question:
Please identify and explain the relevant military criteria (rank, years of service, area of operation, etc.) and explain the medical significance for limiting the selection to those particular individuals.

Answer:
The selection criteria for the Agent Orange Study as listed in the original protocol were: U.S. Army draftees and single term enlistees, pay grades E1 through E5, one tour of duty in Vietnam, no more than 90 days absent (exclusive of R & R leave) of the scheduled 12 month tour, and period of service during 1967 and 1968. The last two criteria were changed as follows to allow more men to qualify: at least 6 months in a combat unit in III Corps and the period of service between October 1, 1966 and March 31, 1969.

Regarding the significance of limiting the selection of veterans, it is critical to the methodology and design of the study that the cohorts be as similar as possible for all health risk factors other than the exposure of interest, i.e. herbicides in Vietnam. If the

groups are not comparable in terms of other health risk factors, then it would be difficult to sort out the possible reasons for any difference in health status. For example, the exclusion of officers is based on the need to make the groups as homogeneous as possible with respect to preexisting demographic factors which could influence health. Also, the time in Vietnam requirement helps ensure that the exposed and unexposed cohorts are comparable with respect to other exposures that might have occurred in Vietnam which could cause health problems.

R3. Question:
How many men must be included in the study to meet your minimal requirements?

Answer:
The original study was based on a three cohort design with 6,000 interviews and 2,000 medical examinations per cohort, for a total of 18,000 interviews and 6,000 medical examinations. Since it appears that finding unexposed veterans is not a problem (as anticipated), an Agent Orange Exposure Study (if conducted) would probably consist of two cohorts each with 6,000 interviews and 2,000 medical examinations, for a total of 12,000 interviews and 4,000 medical examinations.

R4. Question:
a. In your testimony (page 9), you said that two reports on exposure assessment indicate that is was possible to identify relatively few veterans with probably heavy exposure using information available to the environmental support group. What number constitutes a "relatively few veterans" and what constituted "probably heavy exposure?"
b. The testimony also indicates (page 10) that only a small proportion of men in the seven pre-test battalions had a likelihood of significant exposure to recorded Agent Orange sprays. Please quantify and explain what constitutes a "small proportion."

Answer:
a. The following table summarizes the number of herbicide encounters for the first 5,000 men for whom we obtained location information from ESG during 1985. (A man has an "encounter" for each day that his company (or part thereof) was known to be within 2 kilometers of a spray, during the first six days after application).

percentile	25%	50%	75%	90%	95%	maximum
number of encounters:	0	0	1	5	8	69

These results imply, for example, that 75% of these 5,000 men had one or fewer documented encounters, and that 90% of these 5,000 men had five or fewer encounters. A "cutoff" that delineates those men with "probable exposure" is difficult to define, but if a cutoff of eight were used then only about 5% of these men would have met that criterion. (Note: For some companies on some days, no location was recorded on the computer tapes we had available. Such missing information was imputed by ESG during the pilot study, so that scores obtained during the later pilot study may differ somewhat).

b. "A small proportion" is less than one in sixty serving in combat battalions in III Corps of Vietnam at the time of the greatest number of herbicide operations.

R5. Question:
You have concluded that any study of ground troops dependent on military records and the ascertainment of exposure is defective and inconclusive unless an additional method to verify exposure is developed. Having rejected the measurement of TCDD levels in fat, the testimony indicates that a system involving blood measurement is presently being evaluated. Please advise when the evaluation began, where the research is being conducted, the identity of the scientists and/or technical people involved at either HHS or CDC in the study, and when Congress might expect your preliminary conclusions to be reported.

Answer:
The Centers for Disease Control did initial work on measuring serum levels of 2,3,7,8-TCDD in 1983. At that time, state-of-the-art technology in high resolution gas chromatography mass spectrometry was not adequate to detect 2,3,7,8-TCDD in the low parts per quadrillion found in serum. As this technology progressed, more intensive development of a serum method proceeded starting approximately December 1985. The Director of the Division of Environmental Health Laboratory Sciences (EHLS), CEH, is Eric Sampson Ph.D.; the Assistant Director for Science is James Pirkle, M.D, Ph.D.; the Chief of the Toxicology Branch is Larry Needham Ph.D.; and the Supervisor directly over the serum method development is Don Patterson, Ph.D. Preliminary conclusions on the validity of the method and the correlation between 2,3,7,8-TCDD levels in serum and adipose will be available in early September 1986.

R6. Question:
What methods, if any, were employed by other countries during their research on this issue relative to civilian and/or military use in damage?

Answer:
Other studies concerning dioxin's effects have employed several diverse methods. Unfortunately, the goals, limitations of available data, and conditions in the present study differ in key ways from those of other studies so that the techniques used in these other studies are generally inappropriate. This question has also been addressed by the Subpanel of the Agent Orange Working Group Science Panel which concluded that "....no useful model exists from current epidemiologic studies that adequately addresses the problems inherent in identifying an exposed cohort of Vietnam veterans who had served in ground combat operation in Vietnam." Other methods have included:

1. comparison of the health of Vietnam veterans with that of other veterans (not directly a study of Agent Orange)
2. comparison of health of men who sprayed herbicides, either in Vietnam or elsewhere, with that of other men (addresses effects of herbicide, and/or Agent Orange, but not among veterans typical of the majority who served in Vietnam)
3. comparison of the health of men who manufactured herbicides with that of other men (addresses effects of occupational exposures)
4. studies of the health of citizens exposed after an industrial accident (e.g. Seveso: important differences since exposure resulted from a single, well-documented exposure)
5. studies of the health of residents in an area sprayed by contaminated waste oil (important differences, since exposure could be tied to residence in contaminated areas)

Finally, Stellman and Stellman (article attached) suggested a probabilistic exposure index similar to that proposed previously by CDC. While a modification of their method (or that previously proposed by CDC) might provide useful information particularly if effects of dioxin could be documented, the limitations of existing military records are such that important effects could be missed, thereby reducing substantially the scientific value of the study.

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R7. Question:
Please advise the minimal amount of documentation required to be provided by ESG to qualify a veteran as having been "exposed" or "unexposed" to the dioxin.

Answer:
Because of the problems associated with potential misclassification due to lack of data on individual's daily location and incomplete spray records, it is not possible at this time to define criteria for selecting exposed and unexposed veterans. Once a validation study is completed, these criteria will be defined if the results of the validation study indicate it is scientifically possible to separate exposed from unexposed veterans.

R8. Question:
Can you identify the scientists and/or technicians who have been assigned to the exposure study? Please further quantify the total number of personnel working on the study both full- and part-time. Please also identify individual responsibilities for research and the physical locations of research efforts.

Answer:
The total number of positions allocated to the Agent Orange Projects is 55, which includes secretaries, contract specialists, and other administrative support positions, in addition to the scientific and management staff. A breakdown of scientific and management staff is as follows: Eight Medical Doctors--four with additional Doctorates in either Biostatistics or Epidemiology and three with Masters in Public Health; four Doctoral level Epidemiologists; one Doctoral level Psychologist; three Doctoral level Statisticians; five Masters level Statisticians; one Nurse; five Computer Programmers; two Masters level Public Health Managers; and four Public Health Advisors/Managers. All staff are located at CDC in Atlanta except one Public Health Advisor who is stationed at Lovelace Medical Foundation in Albuquerque, New Mexico where the medical examinations are conducted. The primary work on the issue of exposure assessment is carried out by the statistical staff of the Agent Orange Projects under the supervision of the Chief Scientist, the Project Director, and the Director of the Center for Environmental Health. We also use several senior level outside consultants (statisticians, psychologists, neurologists, etc.) and the Institute of Medicine to provide input and peer review of our work. Between FY 1983 and FY 1986, approximately one-half of all Agent Orange Projects staff time has been spent on the Agent Orange Exposure Study. In addition, while CDC is reimbursed for overhead costs relating to this project, other support is provided by the Office of the Director, CDC, and the Office of the Director, CEH, that is not charged to the project.

R9. Question:
Is there any relationship between the Vietnam Experience Study and various criteria used to identify cohorts and protocol for that effort in the exposure group design and protocol? In other words, was either the experience or the cancer study examined to determine if any of the criteria might be applicable for use during the exposure study?

Answer:
The selection/qualifying criteria for the Vietnam Experience Study (VES) were similar, but not identical, to those for the Agent Orange Exposure Study. To increase comparability between those who served in Vietnam and those who served elsewhere, the selection for the VES was restricted to veterans who were:

1) U.S. Army veterans in the non-officer ranks (grades E1 through E5)
2) served only one term of enlistment
3) entered military service for the first time between January 1965 and December 1971.

The basic criteria of U.S. Army veterans in pay grades E1 through E5 who were single term enlistees are the same for the Agent Orange Exposure Study. The additional criteria for the Agent Orange

Exposure Study includes time spent in Vietnam and period of service between October 1966 and March 1969. The Selected Cancers Study requires a different study design (case-control study), and the criteria for inclusion in that study are different and unrelated to the methods for an Agent Orange Exposure Study.

R10. Question:
Describe each of the possible methods of using military records to remedy the exposure problem experienced by CDC that was considered during the deliberations of the Agent Orange Working Group's Science Panel and the subpanel headed by Dr. Young. For each of these possible remedies, please describe the conclusion of the subpanel and, if one was made, by the Science Panel, along with the reasons for that conclusion.

Answer:
As included in the original protocol, the intended method to determine exposure status of veterans in an objective manner was to match the daily locations of recorded herbicide applications, particularly those disseminated through operation ranch hand, with the daily locations of company-sized Army units. It was anticipated that it would be possible to identify a large number of veterans who had been in close proximity to Agent Orange at the time of or soon after spraying on many occasions and an "exposed" cohort could be selected from among those who had had the greatest number of such encounters. An "unexposed" cohort would be selected from among those veterans who had similar assignments in Vietnam, but had few or no such opportunities for exposure.

The exposure problem first encountered by CDC was that, on average, battalion daily records show grid coordinate locations for each company on only about one-half of the days. The environmental support group was able to fill in missing daily locations by contextual reference to all available records, but the process was tedious and somewhat subjective, and required expertise not easily evaluated. The subpanel headed by Dr. Young reviewed these procedures and concluded that all of the relevant records were being appropriately used, and the AOWG science panel concurred with this conclusion.

Another exposure problem, and one not so easily resolved, was that preliminary results failed to identify a group of veterans who clearly had had adequate opportunities for exposure to Agent Orange. Although it was considered that an "exposed" cohort might include veterans who may have been present at the time of spraying, or who may have encountered sprayed areas soon after they were sprayed on a large number of occasions, there were very few individuals who were recorded as having met these criteria. The subpanel reviewed additional pilot data which confirmed the paucity of clearly exposed veterans, and identified several additional problems.

Firstly, different elements of many combat companies were often separated by distances of 2 to 20 kilometers on the same day. Since it is not possible to determine which individuals were in which element, an unknown proportion of veterans will have had fewer opportunities for exposure than their assigned company locations would suggest. Secondly, and of equal importance, expert opinion suggests that a significant number of small base perimeter sprays were never recorded. This could easily result in the inclusion of individuals with opportunities for exposure among the "unexposed" cohort. In either case, the possibility for misclassifcation of exposure status is sufficient to preclude any scientifically valid interpretation of results of a large epidemiological study comparing the health of presumably exposed and unexposed veterans unless an independent measurement of exposure verifies the exposure assessment based on military records.

It is for these reasons that the subpanel recommended that an Agent Orange study would not be done without an additional method to verify exposure, and the science panel concurred with this position.

R11. Question:
Please state whether Major General Murray wrote a report that was considered by Dr. Young's subpanel in which possible methods of using military records for remedying the exposure problem experienced by CDC was discussed. If so, please describe each of the possible methods discussed by Major General Murray. For each of these methods, please explain why the method is inappropriate.

Answer:
The views of all members of the subpanel, including those of General Murray, are included in the final subpanel report.

All possible methods are discussed in the response to R10. General Murray did not offer specific remedies for the exposure assessment problem.

R12. Question:
Has CDC examined the feasibility of using in the current study the exposure methodology that was used in its previous birth defects study? If not, why not? If yes, what was CDC's conclusion and please explain the reasons for this conclusion.

Answer:
The objective of a study of the potential health effects of Agent Orange exposure requires that a group of men who were exposed to Agent Orange be compared to a group of men who were not exposed, the two groups being as similar as possible with respect to other factors which might influence their health. When CDC developed its Agent Orange Exposure Study protocol in 1983, it appeared that the identification of veterans to fit these criteria would need to be based on military unit records. This focus required that the selection of potential participants derive from military units with relatively complete records, and that the voluminous records from a relatively small number of units be reviewed thoroughly.

At the same time that CDC was developing this protocol, it was conducting its study of birth defects. The CDC birth defects study began with babies with and without birth defects and was designed primarily to answer the question of whether Vietnam veterans had an increased risk of having a baby with a birth defect--it was not designed with a focus on Agent Orange. Nevertheless, CDC did attempt to make estimates of veteran's opportunities for exposure to Agent Orange. The fathers of study babies who were Vietnam veterans (about 10% of all study fathers) came from all walks of military life--they had served in a large number of different military units from all branches of the armed services. A thorough review of the unit records for each of these veterans would have been impossible, in part because of the multiple services involved, and in part because of the incompleteness of the records of many of their units.

Instead, a panel of staff from the Army Agent Orange Task Force made an estimation of the opportunities for exposure for each veteran, based on a mixture of objective and subjective criteria. In describing the Agent Orange Exposures Index, the full CDC report on this study stated that "It must be emphasized that this index, as it applies to individual veterans, does not necessarily reflect true levels of Agent Orange exposures, and even with respect to opportunities for exposure, its accuracy is unknown. The score assigned to any particular individual is only the panel's considered opinion about the opportunities for exposure an individual may have had."

R13. Question:
If it is CDC's determination that the exposure methodology used in its birth defects study is not scientifically valid enough to use in the current Agent Orange exposure study, please explain why it is scientifically valid enough to use in the birth defects study.

Answer:
The Agent Orange Exposure Opportunity Index, as pointed out above, is of unknown accuracy, and was considered a less desirable methodology for a study specifically designed to assess the health effects of Agent Orange. The context in which CDC did use its Exposure Opportunity Index was that of an addition to a study designed to assess the risks of having babies with birth defects for Vietnam veterans in general.

ATTACHMENT 1

4. Study Procedures

4.1. Selection of Study Subjects

The selection of study subjects for the two cohort studies will be based on a review of military records by the Army Agent Orange Task Force (AAOTF) according to criteria set forth below. Selection of subjects for the Agent Orange study will depend on a simultaneous consideration of the position of U.S. troops in Vietnam and the times and locations of herbicide applications as indicated by extant records; neither the location of troops nor their proximity to herbicide applications will play a part in the choice of subjects for the Vietnam Experience study. Choice of subjects for the Selected Cancers study will derive from work done by CDC and the cancer registries participating in the study. Since this study is a case-control study, beginning with persons with the cancers and those without, military records will not be used as a part of the selection process, although they will be used as an aid to assessing exposure to herbicide among subjects who turn out to be Vietnam veterans.

CDC intends to limit individuals included in all three proposed studies to men. The exclusive attention to males does not derive from a lack of concern about the health of those relatively few females who did serve in Vietnam. Rather, this decision is based on CDC's belief that if females are to be studied, they should be studied separately in sufficient numbers to allow meaningful conclusions to be reached about them as a group. Moreover, any study of women would require somewhat different sampling strategies and different emphases in interviews and medical examinations. CDC is concerned that a study of female veterans might be difficult to implement because of the probability that female veterans, once identified from military records, will be harder to locate than men because of the name changes which will have occurred because of marriages after discharge. The AAOTF and CDC are assessing the locatability of female Vietnam veterans. If this assessment proves that it is indeed possible to locate a sufficient proportion of them, CDC will design a separate study and prepare a protocol for review and possible funding. Such a study would probably most resemble the Vietnam Experience study proposed here for males, but a study of cancers similar to that proposed for males will not be possible -- too few women served in Vietnam for any meaningful case-control study to be done.

4.1.1. Agent Orange Study

CDC proposes to limit this study to draftees and single-term enlistees in the non-officer ranks who served in the Army (grades E1 through E5 only); selection will be further limited to those who had only one tour of duty in Vietnam. Exclusion of officers is based primarily on a desire to make the groups as homogeneous as possible with respect to pre-existing demographic factors which could influence health. In addition, the inclusion of officers might require substantially increased record review to assess herbicide exposure potential (see below) because of multiple tours of duty in Vietnam.

Exclusive focus on veterans of the Army is chosen for several reasons. The Army had a much greater proportion of draftees than the other services, and we believe that it is important to include substantial numbers of them in the study. Use of draftees will probably make achieving a balance on such

factors as training, military occupational specialties, and pre-existing demographic factors easier. Inclusion of substantial numbers of draftees is also motivated by a desire to try to assess the possible association between volunteerism and health. (If, however, a large percentage of enlistees joined the Army because they felt that the draft was inevitable, such an assessment may not be possible.) CDC proposes to exclude the Marine Corps in part because its men were mostly volunteers and in part to limit the amount of records review required to select study subjects (the reasons for this will be better appreciated after the selection process is described). In addition, the AAOTF has worked most extensively with the records of the U.S. Army, has become most familiar with them, and is most confident about their quality. Moreover, the Air Force did not keep records that show the daily geographical placement of personnel, and rather limited numbers of Navy servicemen were stationed on land in the Vietnam theater. Even though all study participants will be males in the non-officer ranks who were in the Army, the results will probably be useful in making inferences about all men who had similar ground experiences and possible herbicide exposures in Vietnam; if there are no sex-specific effects, the same may be said about females.

As noted previously, three cohorts of men will be chosen for the Agent Orange study. The first two, which will differ with respect to the likelihood of exposure to herbicides, will be chosen from III Corps (an area where herbicides were used extensively) during the same period of time, 1967-1968. This will be done to make the two as similar as possible with regard to the nature of their service experience -- similar with regard to, for example, type of terrain, indigenous diseases, and intensity of combat. To enhance the possibility of including soldiers who may have been exposed to herbicides, we will select the men included in these first two cohorts exclusively from combat battalions. Since these two cohorts will be chosen from an area where herbicides were extensively used, there is a potential for exposure misclassification. The third cohort will therefore be chosen from an area where there is good evidence that herbicides were not used. According to the AAOTF staff, this third cohort probably cannot be exclusively derived from combat battalions.

Veterans to be included in the first two Agent Orange study cohorts will be selected by a multi-step review of military records, beginning with the selection of a geographical area of consideration and ending with the choice of individual soldiers. Since many of the proposed procedures are untested, modification, indeed even a recommendation not to proceed with an Agent Orange study, may be required after pilot study assessments (see section 4.5.1.1. below). In summary, the steps required are:

1) select a geographical area and time of interest - this will be III Corps and 1967-1968
2) determine which of the battalions stationed in III Corps in 1967-1968 have acceptable records
3) choose a random sample of 50 battalions (250 companies) from among all battalions with acceptable records
4) choose 2 random subsamples of 25 battalions (125 companies) each from the 50 battalions chosen in step 3
5) abstract selected companies' locations for subsample 1 on all days in 1967-1968

6) using the "Herbs" and "Services Herbs" tapes, score the herbicide encounters of the 125 companies of subsample 1 on all days
7) rank the 125 companies of subsample 1 with respect to their cumulative herbicide encounters
8) choose men for the "likely exposed" cohort from companies at the top of the ranked list and men for the "likely not exposed" cohort from those at the bottom of the list
9) using the "Herbs" and "Services Herbs" records, score individual men chosen in step 8 for their herbicide encounters according to the scoring schemes used for battalions (step 6).
10) repeat steps 5 through 9 for the 25 battalions comprising subsample 2, with the following modification: rank herbicide encounters using the 125 companies of the 25 battalions of subsample 2 and the companies of subsample 1 which were not chosen in the first iteration of step 8

The rationale for these steps is presented below.

To limit the amount of records review required, we first restricted, on the advice of the AAOTF, the geographical area of consideration to III Corps and the time period to 1967-1968. This area and time period were selected because of a variety of factors, including the number of Ranch Hand missions and U.S. troop strength, which was near peak. The AAOTF has determined that about 110-120 Army combat battalions were stationed in III Corps at some point during that time (usual battalion strength was 1,000). The records of the companies attached to battalions determined to have served in III Corps will be the major source of information about troop locations.

The second step in the selection process will consist of a review of General Services Administration (GSA) documents to ascertain which battalion records appear to have unacceptable time gaps (if gaps appear in battalion records, it may be possible to supplement them with division and brigade level records, and this will be done when feasible). CDC does not believe that it is necessarily wise to exclude a unit simply because some of its records are missing -- units with missing records could have had more or less exposure to herbicides than units with complete records. Therefore, CDC proposes to apply the following criteria regarding records quality: if a battalion has more than 30 contiguous days of absent records or an aggregate of more than 60 days' absent records for the period 1967-1968, the unit will be considered unsuitable for inclusion in the study. If very few units are found to have gaps of this magnitude, more stringent criteria can perhaps be used. For each of the combat battalions located in III Corps in 1967-1968, the AAOTF will summarize the condition of the records as indicated in the GSA documents.

The third step will be the choice of a random sample of 50 battalions (250 companies) from among those judged suitable during the second step. Step four will involve splitting the sample of 50 battalions into random halves of 25 battalions each. Fifty battalions will be sampled in order to limit the quantity of records review required, but this sampling should provide a reasonable estimation of the range of herbicide encounters (next paragraph). CDC believes that this is an important issue -- at this point the frequency and nature of troop herbicide encounters is largely a matter of conjecture. As noted before, the records available will never permit an unambiguous assessment of exposures, but this approach will help to place a frame of

objectivity around the issue, at least for men in Army combat units in III Corps in 1967-1968. Step five will involve abstracting from company records (or battalion records, if necessary) all locations recorded for the selected companies on each day during 1967-1968.

The purpose of dividing the sample of 50 battalions into halves is to increase the speed with which CDC can proceed with the interviews and examinations. The AAOTF estimates that it will take 18 months to abstract location information for all 50 battalions and that it will take 12 months to do it for the first 25 battalions. Step five will involve abstracting from company records (or battalion records, if necessary) all locations recorded for the selected companies on each day during 1967-1968.

In step six, CDC will check the company locations against the locations of herbicide applications as recorded on the "Herbs" and "Services Herbs" tapes. The "Herbs" tape contains computerized records of Ranch Hand missions (time, place, type, and amount of herbicide). The National Academy of Sciences report (1974) on the effects of herbicide usage in Vietnam contains a relatively limited assessment of the accuracy of these records. CDC finds the results of this investigation encouraging, but doubt about accuracy exists in some quarters today. CDC has requested that the National Academy make available the results of other checks done at the time and that it look into the possibility of further accuracy checks. The "Services Herbs" tape primarily contains records of non-Ranch Hand herbicide applications (e.g., base perimeter sprayings). This set of data has been put together by the AAOTF from a review of a variety of military records; the degree of completeness of the "Services Herbs" data set is unknown.

The number of unit encounters with herbicide applications according to these data sets will be tabulated by at least three systems; other systems may be used if this seems warranted. The first of these systems will have geometrically progressing scores or weights for various space and time distances, and the second will have linear weights. The aggregate scores for these two systems will be based on the products of the time and space scores. The third system, a variant of one proposed by the Department of Defense, will simply count the number of encounters which are at distances of less than 3 days and 2 kilometers. The purpose of these exposure systems is to obtain a spread of unit exposures so that units can be chosen from the top and bottom of the scales. It is desired that the spreads obtained should reflect "meaningful" differences in exposure. Relatively little is known about the environmental fate of herbicides and TCDD, and even less is known about the human pharmacokinetics of these substances. Because of this lack of knowledge, these systems are necessarily arbitrary and this motivates the proposal of three scales. The scorings for the first two systems proposed for preliminary tabulation are indicated below.

Exposure System A.

1. Ranch Hand Missions
   a. Regular Missions -- cross-classified by time after mission (<=1 day, score=16; 2-3 days, score=4; 4-30 days, score=2; and 31-59 days, score=1), distance (<=1 km, score=4; 2-3 km, score=2; 4-8 km, score=1), and type of herbicide.

b. Aborted Missions -- cross-classified and scored as above.

2. Other Herbicide Applications (e.g., perimeter spraying)--for those encounters <= 1 km classified by time and scored as above

Exposure System B.

1. Ranch Hand Missions
   a. Regular Missions -- cross-classified by time after mission (<=1 day, score=4; 2-3 days, score=3; 4-30 days, score=2; and 31-59 days, score=1), distance (<=1 km, score=3; 2-3 km, score=2; 4-8 km, score=1), and type of herbicide.

   b. Aborted Missions -- cross-classified and scored as above.

2. Other Herbicide Applications (e.g., perimeter spraying) -- for those encounters <= 1 km classified by time and scored as above.

As mentioned before, the various encounters will be weighted by the product of the time and distance scores; each encounter of a unit with a particular herbicide application will be counted in only one time and one distance category. For example, using Exposure System A, an encounter with a Ranch Hand mission within 1 day and 1 km would receive a score of 64, as would an encounter with a base perimeter application within 1 day (small bases); an encounter with a Ranch Hand application within 4-30 days and 2-3 kilometers would get a score of 4. Using the third (modified Department of Defense) system, any encounter which occurs within the 3 day-2 kilometer limit would receive a score of 1. For each of the 3 exposure systems, the daily scores will then be summed over all days in 1967-1968 for each company.

Next, the 125 or so companies of subsample 1 will be ranked on their summed encounter scores. If there is good agreement in the rankings provided by the three systems, those at the top of the lists will provide individuals for the "likely exposed" cohort and those at the bottom will contribute to the "likely not exposed" group. If there are substantial disparities in the rankings provided by the three systems, then roughly 1/3 of each of the two cohorts will be chosen from the top and bottom of each of the rankings. At this time it is unclear how many companies will have to be selected to provide the requisite number of individuals for these 2 cohorts, but it will probably be on the order of 50 to 60 from the top and a like number from the bottom (of both subsamples combined). If 55 companies each provide 150 suitable individuals, this number will allow some loss because of non-participation and will yield the number desired for each of the cohorts (see section 4.4.1.). About 40% of the final sample of men will be derived from subsample 1, and the remainder will be chosen after the re-ranking in the second iteration of steps 5 through 8.

The desire to omit the Marine Corps from this study can now be more easily understood. If Marines were included, the records review and other selection tasks to this point would have to be done separately for them because they were largely stationed in I Corps, and this would cause delay.

The next step will be the choice of individual soldiers from the selected units. This process will begin with a review of company morning reports.

Individuals who appear to meet the criteria with respect to type of entry into the service (draftee or single-term enlistee), are in the non-officer ranks, and whose 1- year Vietnam tour began and ended during 1967-1968 will be considered potentially eligible for inclusion in one of the cohorts. For those who appear to be eligible, the AAOTF will also document their presence or absence with the selected units on each of the days during the 2-year period 1967-1968. Those individuals who were absent from their units for more than 90 days of their scheduled 12-month tours (exclusive of their regular R&R leave) will be considered ineligible for final selection. The AAOTF will also document the reasons for all absences for both the selected men and those men who would be eligible except for their absences. Thus, this process will provide CDC with, inter alia, a measure of combat intensity, since absences for reason of casualty will be recorded. Individual personnel folders will be obtained by the AAOTF from the National Personnel Records Center in St. Louis for soldiers considered eligible. The AAOTF staff will abstract certain identifying and service (e.g., military occupational specialty) information from the individual personnel folders and forward the information to CDC on an incremental basis so that CDC can begin the process of locating the veterans and soliciting their participation in the studies. Later, in step 9, individual soldiers will be classified with respect to exposure to herbicides by a scheme similar to that noted above. At this step some men drawn from units at the upper end of the exposure scale may be found to have "low" individual exposure scores and vice versa. Such men might be assigned to the other cohort or they might be omitted from the study altogether.

The third cohort for the Agent Orange study will be selected by a different method. Areas in Vietnam where there would have been no reason for herbicide usage will be identified by the AAOTF and a roster of units which served in, and only in, those areas in 1967-1968 compiled. The staff of the AAOTF has suggested that Cam Ranh Bay or Vung Tau might be examples of such areas. CDC will check the locations of these areas against the herbicide usage records to ensure that there was no herbicide use. Enough units will be randomly chosen from this roster for the required number of individuals to be included in the study. The eligibility criteria for selecting individuals from within the selected units will be the same as those used for the first two cohorts. The AAOTF will provide CDC with the same sort of identifying, service, and absence information that it provides for those individuals included in the two other cohorts.

4.1.2. Vietnam Experience Study

The procedures for selecting individuals for the Vietnam Experience study will be substantially different from those used for the Agent Orange study -- the process will start with the selection of individual personnel files in the National Personnel Records Center in St. Louis rather than with the selection of military units. We understand that, for draftees and single-term enlistees in Army combat units, assignment to Vietnam or to some other part of the world was essentially a random process, but this was probably not the case for other services. Since the desire is to compare men who went to Vietnam with men who did not, but who had a more or less equal chance of being assigned to Vietnam, CDC also proposes to limit this study to Army veterans in the non-officer ranks (grades E1 through E5).

ATTACHMENT 2

American Journal of Industrial Medicine 9:305–321 (1986)

Estimation of Exposure to Agent Orange and Other Defoliants Among American Troops in Vietnam: A Methodological Approach

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Two pivotal problems in determining whether exposure to herbicides has caused disease in Vietnam veterans or their offspring are definition of which troops were exposed and extent of exposure. The DoD HERBS tape is the most complete publicly available record of herbicide spraying in Vietnam. It contains about 17,000 records consisting of coordinates of spray missions, dates, chemical agent, quantity and area sprayed, and mission purpose. We have developed a set of discrete and continuous indexes of probability of exposure to herbicides for individual veterans. These probability indexes are based on HERBS tape spray data and on locations and dates of service derived from a place-and-date matrix completed by the veteran. They can take into account a conservative estimate of environmental persistence of herbicide by using first-order exponential decay kinetics with an estimated half-life of dioxin. Mean values for the continuous exposure probability indexes were significantly greater among veterans judged to be exposed according to self-reported job titles and specific military experiences than among men judged unlikely to have been exposed. Probabilistic exposure indexes based on the HERBS tape for classification of likely exposure to herbicides in South Vietnam during 1965–1971 appear to be well suited for comparative classification of veterans and hence for use in epidemiologic studies.

Key words: Agent Orange, phenoxy herbicides, TCDD, dioxin, Vietnam veterans

INTRODUCTION

The possible human health effects associated with the systematic spraying of large portions of South Vietnam with defoliating chemicals carried out by the United States during 1962–1971 are a matter of great public and professional debate and concern. During that time, nearly 6 million acres of land were sprayed. Agent Orange, a 1:1 mixture of the n-butyl esters of 2,4-D and 2,4,5-T, was the main herbicide used. Agents White (2,4-D and picloram) and Blue (cacodylic acid) were also used but in lesser amounts [Young et al, 1978].

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Accepted for publication September 17, 1985.

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The ingredients of Agent Orange are known to be toxic. 2,4,5-T is embryotoxic and teratogenic to the mouse [Courtney and Moore, 1971; Neubert and Dillmann, 1972; Hood et al, 1979], causes fetal anomalies in hamsters [Collins and Williams, 1971], and induces a variety of genotoxic effects in numerous animal and plant species [Grant, 1979]. 2,4-D in large doses can poison experimental animals and livestock [Rowe and Hymas, 1954; Fenton, 1984] and is neurotoxic to humans [Goldstein et al, 1959]. When given orally to rats, 2,4-D was found to be embryotoxic and fetotoxic but not teratogenic [Schwetz et al, 1971].

The 2,4,5-T used in Agent Orange was also heavily contaminated with 2,3,7,8-tetrachloro-p-dibenzodioxin (TCDD) and its congeners [Young et al, 1978]. The mean concentration of TCDD in Agent Orange was 2 ppm. Individual concentrations ranged from 0.05 to about 30 ppm [Young et al, 1978]. In laboratory animals, TCDD was found to be extremely toxic [Huff et al, 1980]. The LD50 for guinea pigs is less than 2 μg/kg of body weight [Huff et al, 1980; Schwetz et al, 1973]. At subacute doses, it produces many other systemic effects. TCDD is also embryotoxic and teratogenic to several strains of rats and mice [Courtney and Moore, 1971] and has been found to be carcinogenic by several routes of administration [International Agency for Research on Cancer, 1977; Van Miller et al, 1977; Kociba et al, 1978].

The effects of TCDD on humans are not so well established as those for animals. Human health effects are known chiefly from studies following industrial accidents and other occupational exposures. Clinical evaluation of workers and others exposed to dioxin has produced a wide range of dermatological, metabolic, neurological, and behavioral effects [Huff et al, 1980]. The best known and most widely recognized of these is chloracne, which is often described as the "hallmark" of dioxin exposure. However, many of these other conditions can result from exposure without chloracne being present [May, 1973; Oliver, 1975; Pazderova-Vejlupkova et al, 1981].

These and other observations have led to the hypothesis that soldiers exposed to Agent Orange during military service in Vietnam are at increased risk for various acute and chronic diseases and for fathering children with birth defects.

Currently a number of studies are being conducted on the health of Vietnam veterans and their offspring. The majority are planned as long-term investigations and will not be completed for some years [American Medical Association, 1981]. A preliminary account of the Baseline Morbidity Study of Air Force personnel who conducted aerial herbicide dissemination missions in Vietnam (Operation Ranch Hand) showed no significant differences compared to control groups in conception outcomes such as prematurity, miscarriages, stillbirths, or "severe" birth defects but did observe an excess of "minor" defects as well as a significant excess of neonatal deaths and physical handicaps [Lathrop et al, 1984].

Among the studies now complete, a case-control study of babies born in the metropolitan Atlanta area concluded that Vietnam veterans in general did not have an increased risk of fathering babies with defects (all types combined) [Erickson et al, 1984a]. However, veterans judged to be "exposed" to Agent Orange had significantly higher risks of having children with birth defects including spina bifida, cleft lip with or without cleft palate, and a miscellaneous constellation of neoplasms. Donovan et al [1984] have reported that the risk for Australian Vietnam veterans to have fathered a child with a birth defect was no different from that of other Australian men.

In all these studies, one of the most difficult problems has been that of defining exposure. Accurate data on individual exposure is not available. Information on

general herbicide usage exists but has so far proved difficult to translate into individual exposures.

Lathrop et al [1984, Chapter VIII] computed an average exposure index for each Ranch Hand subject by dividing the total gallonage of TCDD-containing herbicide sprayed in the entire Vietnam theater during the subject's tour of duty by the number of airmen with duties equivalent to that subject during the same time period. This measure does not take into account individual exposures at specific times and places.

Erickson et al [1984b] also used two different exposure indices. The first was a self-report obtained by asking the subject "Do you think you were ever exposed in any way to herbicides, like Agent Orange?" (p 228). A more objective "Exposure Opportunity Index" (EOI) was also developed, whereby a "panel of specialists familiar with existing records of herbicide spraying in Vietnam used a mixture of objective and subjective methods" to estimate possible exposures for individual veterans (p 23). Two separate EOI scorings were done, one based on occupation, location, and time recorded in military records ("records-based score") and one based on similar information obtained from direct interviews with the veterans ("interview-based score"). Despite this incorporation of external information, the EOI scoring system was judged by authors of the study to be "a generally subjective evaluation." Furthermore, Erickson et al have commented that the mixture of effects reported could easily have resulted from errors of misclassification [Erickson et al, 1984a].

Thus there is a contrast between the highly technology-intensive techniques for evaluating the medical status of veterans and the less sophisticated methods of estimating exposure to herbicides developed to date. Despite these difficulties, however, one valuable source of objective, specific information on the patterns and extent of herbicide usage in Vietnam, the so-called HERBS tape, developed by the U.S. Army, can be useful in developing estimates of exposures. Indeed, this data source was used to derive the "records-based score" in the Atlanta birth defects study, although the exact way in which the information was incorporated into the EOI was not described [Erickson et al, 1984b, p 23].

The purpose of this paper is to investigate the use of the HERBS tape to see to what extent it can be a useful, objective source for exposure classification for individual veterans. The data file contained on this tape consists of an assembly of over 17,000 records, each describing a piece of an herbicide spray mission. The information provided within each tape record is summarized in Table I. Besides location, the tape records also contain data on dates of spraying, the type of mission, which of the three herbicides was used, the volume used, and the area sprayed. The

TABLE I. Data Contained on HERBS Tape

Date (month/day/year)
Combat tactical zone (I, II, III, IV)
Mission number
Agent (Orange, White, Blue)
No. of gallons
Type of mission (defoliation, crop destruction, etc)
Area sprayed (hectares)
Leg designator: 1A, 1B, etc
UTM coordinate of leg

HERBS tape was kindly made available to us by the Records Management Group of the office of the Adjutant General of the U.S. Army.

MATERIALS AND METHODS

Resource: DoD HERBS Tape

The 1990 version of the HERBS tape that we analyzed contained data on 6,475 distinct missions. A mission typically consisted of several legs, each one representing a continuous spray route, possibly including legs. Each HERBS tape record refers to a single coordinate point on the map of Vietnam. Continuity of spray runs from point to point on the map (and from one HERBS tape record to the next) is indicated by letter-numeral combinations called leg designators (1A, 1B, etc). The numeral of the leg indicates the number of the run within the mission to which the associated coordinate belongs, and the letter designates the leg within that run. The coordinates are keyed to the Universal Transverse Mercator (UTM) system, which is a rectangular grid ruled off in 100,000-meter subgrids.

The diagram in Figure 1 shows two legs of a mission flown near Pleiku. The plane turned its spray on at 1A, and continued to spray as it flew on to 1B, 1C, 1D, 1E, and 1F. It turned the spray off, flew to position 2A, and sprayed until 2B.

For our calculations, we used established coordinates of vertices only, rather than center-points or average locations, because low-flying spray planes were frequently fired on and forced to deviate from a straight-line course.

Construction of Exposure Scales

The method described here consists of several approaches used separately and in conjunction to provide different probabilistic exposure indices for the Vietnam veteran in question. The parts are: *self-reported history* by the veteran of the dates and locations he served in Vietnam as recorded in a precoded and tested Vietnam

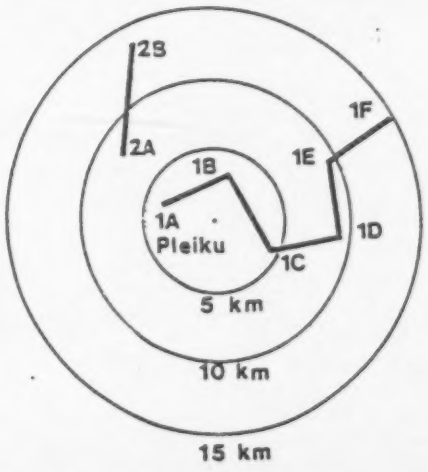

Fig. 1. Representation of a typical spray mission flown near Pleiku. Plane sprayed continuously 1A to 1F, flew without spraying to 2A, then sprayed from 2A to 2B. Number of vertices or falling within radii of 5, 10, and 15 km are 3, 6, and 8, respectively.

place-and-date matrix developed for this study, and described more fully below; 2) *self-reported descriptions* of military service, jobs, and experiences using a pretested, precoded questionnaire; 3) *discrete exposure indices*, C_5, C_{10}, C_{15}, which are counts of the number of times a veteran was located within a specified radius (5, 10, or 15 km) from any of the spray locations on the HERBS tape, at times when spraying occurred; these indices incorporate information supplied by the veteran using the Vietnam place-and-date matrix; 4) *continuous exposure indices:* i) E_1, a continuous distance-weighted measure of how close in distance to actual defoliation missions the veteran was during his tour of duty as calculated using the HERBS tape data and the veteran's military experience and place-and-date matrix; ii) E_2, an integrated estimate combining both direct exposure, as in i, and indirect exposure derived from residual herbicides, in an area of duty where spraying occurred prior to the veteran's service in that area, using the HERBS tape data and the veteran's place-and-date matrix; iii) E_3, an integrated exposure index combining both i and ii above that allows for direct exposure, indirect exposure through environmental persistence, and distance from spraying missions during a veteran's tour of duty.

The discrete indices simply count the number of likely exposures that could have occurred within a specified radius of a veteran's location, whereas the continuous indices can take into account concurrent exposures *plus* potential exposures to residual herbicides from all previous spraying missions that took place within 15 km of a given location.

The continuous indices are defined by three related continuous exposure measures (E_1–E_3). The first, represented by equation 1, defines the index of exposure, E_1, as the sum of the reciprocals of the distances of all spray locations from a given position.

$$E_1 = C_o \sum_{ij} (1/D_{ij}), \tag{1}$$

where C_o represents the initial concentration of the herbicide in each of the spraying missions, D_{ij} is the distance from the veteran's ith known location to the jth coordinate on the tape, and (i,j) pairs are restricted to those HERBS tape records j whose dates coincide with the veteran's assignment dates at location i.

For the continuous index, E_1, we only use spray dates included within the veteran's stay at location i, which do not include the effects of spraying during previous missions. The use of reciprocal distances in this index gives higher weight to closer "hits" in the summation. For computational convenience, the sum is restricted to all distances less than or equal to 15 km; hits at greater distances contribute negligibly to the sum.

The second continuous measure of exposure, E_2, is given by equation 2. E_2 has been constructed to consider the environmental persistence of an exposure over time.

$$E_2 = C_o \sum_{ij} \int_{t_{1,ij}}^{t_{2,ij}} e^{-\lambda t}\, dt, \tag{2}$$

where λ is a decay constant and t is time. For an individual veteran, the expression in eq. 2 is integrated mathematically from $t = t_{1,ij}$ to $t = t_{2,ij}$, where $t_{1,ij}$ is the first date

he was stationed at location i and $t_{2,ij}$ is the date he left it. The integral is evaluated for each location j on the HERBS tape within 15 km of veteran location i, provided the herbicide spraying occurred prior to $t_{2,ij}$. If the spraying occurred after time $t_{1,ij}$, then the lower limit of the integral is set to the actual date of spraying.

E_2 takes into account explicitly the fact that once sprayed Agent Orange and other herbicides will not instantaneously "disappear" but will be present in the environment and will be degraded as time passes. Therefore, the index E_2 gives higher weight to more recent sprayings while "remembering" past sprayings but weighting them according to an exponential decay law.

A third index, E_3, given in equation 3, is a composite of E_1 and E_2, which combines environmental persistence with reciprocal distance to give higher weight to more recent sprayings as well as to closer hits.

$$E_3 = C_o \sum_{ij} (1/D_{ij}) \int_{t_{1,ij}}^{t_{2,ij}} e^{-\lambda t}\, dt, \tag{3}$$

where the indices i and j and times $t_{1,ij}$ and $t_{2,ij}$, are as defined above. In these equations, we have assigned a constant concentration C_o to the herbicide used in all missions.

For both E_2 and E_3, we have used a first-order exponential decay with rate constant λ. As with any first-order decay, the half-life, τ, is given by

$$\tau_{1/2} = \frac{\ln 2}{\lambda} \tag{4}$$

The choice of a first-order decay law in the present study, that is, a constant half-life, is both an approximation and a conservative approach; it assumes a more rapid disappearance than might actually have occurred. Studies of environmental persistence of TCDD in soil surrounding Seveso, Italy, the site of a large-scale environmental release of TCDD, showed an increase in half-life with time [Di-Domenico et al, 1980]. However, environmental degradation of TCDD in persistence studies conducted on heavily treated soils at test sites in Utah and Florida, observed by Young et al [1976], demonstrated decay consistent with first-order kinetics. In our calculations, we have assumed a half-life of 1 year, as suggested by several studies of TCDD persistence in soil [DiDomenico et al, 1980; Young et al, 1976; Kearny et al, 1972].

On the other hand, it might be that the total amount of herbicide reported sprayed during any one mission did not reach the ground because of jungle cover or otherwise was dispersed in the environment. For these reasons, this approach might overestimate exposure. However, in that these indexes are both probabilistic and relative, the use of the same kinetic equation for all troops should not introduce a systematic bias in any direction. Furthermore, ranking of veterans' exposure scores is insensitive to large changes in λ.

Examples

Two hypothetical examples of this calculation are shown in Figure 1 and in Table II. In the example of Figure 1, a veteran reported that he was present in Pleiku

TABLE II. Number of Herbicide Spray "Hits" Within 5, 10, and 15 km of Six Selected Sites in Vietnam (1965–1971)

Place	No. of spray hits within (km)			Exposure index E_1[a]
	5	10	15	
Tay Ninh	0	5	33	2.814
Chu Lai	2	33	55	6.304
Khe Sanh	15	23	55	8.264
Camp Evans	3	35	110	10.609
Phuoc Vinh	27	144	356	38.958
Pleiku	69	74	121	43.600

[a]Defined by eq 1.

on the date the diagrammed spray mission took place. As is shown in the figure, three vertices fall within 5 km of Pleiku, six fall within 10 km, and all eight fall within 15 km. We call these counts the "number of hits within 5, 10, and 15 km," respectively, and our scheme assigns the veteran exposures $C_5 = 3$, $C_{10} = 6$, and $C_{15} = 8$ for this particular mission. This type of count can be computed for any location in Vietnam whose UTM coordinates are known.

As a second example, we have summed the indices C_5, C_{10}, and C_{15}, which count the total number of "hits" within specific radii, in six towns or other places in Vietnam, where thousands of American troops were stationed: Chu Lai, Khe Sanh, Camp Evans, Pleiku, Tay Ninh, and Phuoc Vinh. Table II shows the total number of such hits falling within 5, 10, and 15 km of these locations, respectively, as well as the total index, E_1, derived from all sprayings from 1965 through 1971. These represent upper limits to exposure indexes that would be calculated for veterans stationed at these locations for shorter periods of time. These sample calculations illustrate how the indices can differentiate exposure classification among combat troops.

Self-Reported Location and Exposure Data

Self-reported history and place-and-date matrix formats were developed in consultation with numerous veterans and other experts on Vietnam geography. A matrix, divided into the four Combat Tactical Zones, or Corps, in Vietnam, I, II, III, and IV, was created in which major villages, locations, and areas heavily used by American troops were listed by the names used by the veterans. The printed matrix was accompanied by a map of Vietnam on which larger towns were also shown. The matrix was designed so that the respondent could indicate up to 98 specific places in Vietnam where he might have served and the dates that he was there.

This method of collecting location and date information data was pretested in 100 California veterans and proved to be a satisfactory data collection instrument. Approximately 70% of questionnaires had sufficiently completed places and dates to calculate the above exposure measures without assistance and without an interview. The questions used in the self-described exposure section are reproduced in Table III.

Subjects were asked whether they had experienced any of the following: been a sprayer on a C-123, helicopter, or boat; had worked at clearing vegetation; had worked as a sprayer or handler of herbicides during shipment; or had slept in or walked through obviously defoliated areas. Subjects were then classified as "ex-

TABLE III. Wording of Questions on Self-Described Exposure to Agent Orange

– In this section we are interested in finding what you remember about being exposed to defoliating herbicides, such as Agent Orange, which were used to kill jungle cover in Southeast Asia. If you believe you were exposed to such a chemical agent, either by directly loading it, spraying it, or entering a freshly sprayed area, we would like you to describe how you were exposed and when.

If you don't remember being directly exposed to herbicides, check here: ___ and go on to next page.

	No	Yes	If yes, No. of weeks
Sprayer on C-123	—	—	—
Sprayer on helicopter	—	—	—
Sprayer on boat	—	—	—
Loader/handler of spray on any of the above	—	—	—
Job involved clearing vegetation and/or patrolling around camp, roads, or clearing free-fire zones	—	—	—
Slept/walked through sprayed areas. Exposed to herbicides used near camp or on roads you traveled on	—	—	—
Handler of spray during storage or shipment	—	—	—

posed" or "not exposed" to each of these spray occupations or to recently sprayed terrain.

This information allowed us to compare the measures of exposure derived from the HERBS tape against the observations, experiences, and military jobs reported by the soldiers.

Application of Algorithms and Analysis of HERBS Tape

We have tested the exposure indices on a sample of 478 veterans selected from a study we have been conducting with the Veterans Education Project of the National Veterans Law Center, American University. Several thousand questionnaires were mailed to veterans participating in a nationwide outreach program sponsored by the Veterans Education Project. The questionnaires solicited information on veterans' health and reproductive outcomes and contained the exposure instruments described above. This sample was clearly highly self-selected, so that it would not be appropriate to generalize directly associations of herbicide exposures with health outcomes from this population to all Vietnam veterans. However, because our present purpose is only to investigate our proposed exposure indices, and not health outcomes, there is nothing inherently biased in using this group to test the exposure algorithms, of which the respondents had no knowledge. This point is discussed again below.

Finally, we have also carried out calculations on the aggregated data contained in the HERBS tape to obtain additional data on overall usage of defoliants and hence to provide more information about potential exposure of American troops in Vietnam during 1965–1971. In addition, we have made estimates of the relative concentration of herbicides used on each of the missions by calculating the ratio of gallons to area sprayed using the data recorded on the tapes.

RESULTS

Overall Patterns and Extent of Defoliation Activities

Quantities of herbicides recorded on the HERBS tape can be compared to previously published estimates of herbicide use in Vietnam as an indicator of the completeness of data available to us. The total volume of Agent Orange recorded on the HERBS tape was 11,197,929 gallons, which differs by less than 0.7% from the quantity reported by the National Academy of Sciences [Committee on the Effects of Herbicides in South Vietnam, 1974]. Similar levels of agreement were observed for Agents Blue and White.

Defoliants were used in Vietnam for a variety of purposes. Figure 2 shows the major reported uses of the three herbicides in Vietnam, defoliation and crop destruction; Figure 3 shows the minor uses reported, related to Vietnamese troop movement and their interdiction. More than 10 million gallons of Agent Orange were sprayed in at least 3,000 separate defoliation missions. Nearly another million gallons of Agent Orange were used in crop-destruction programs. About 5 million gallons of Agent White and 1 million gallons of Agent Blue were also used for these purposes. Approximately 100,000 gallons of Agent Orange were sprayed around the perimeters of bases to deny cover to enemy troops. These latter uses of defoliants might also have led to significant exposure to U.S. troops.

For more than 80% of the missions, the calculated ratio of gallonage to area sprayed, which is a close approximation of concentration, is nearly constant. Fifteen percent of the missions with a substantially different gallon/area ratio occur among

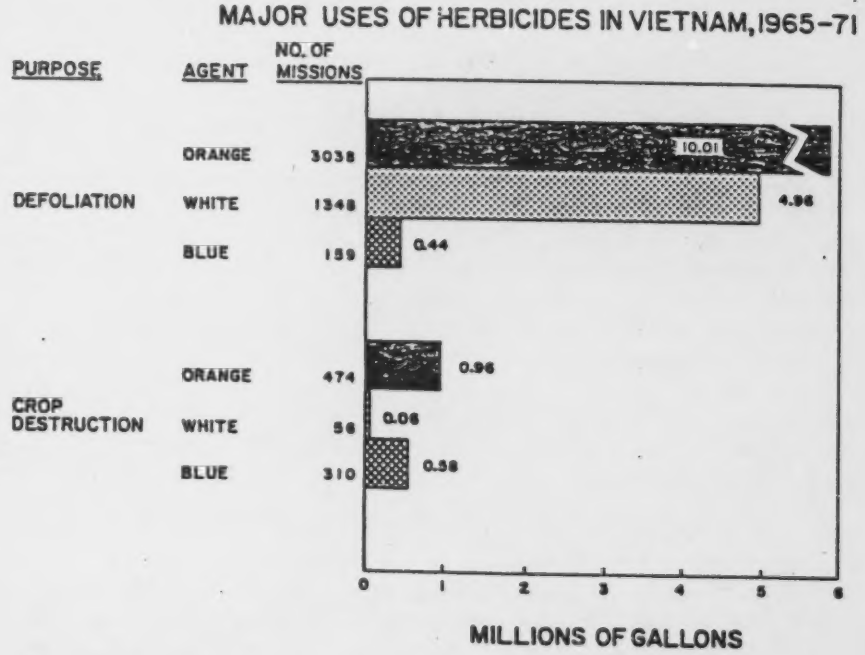

Fig. 2. Quantities of Agents Orange, White, and Blue used in defoliation and crop destruction missions in South Vietnam, 1965–1971.

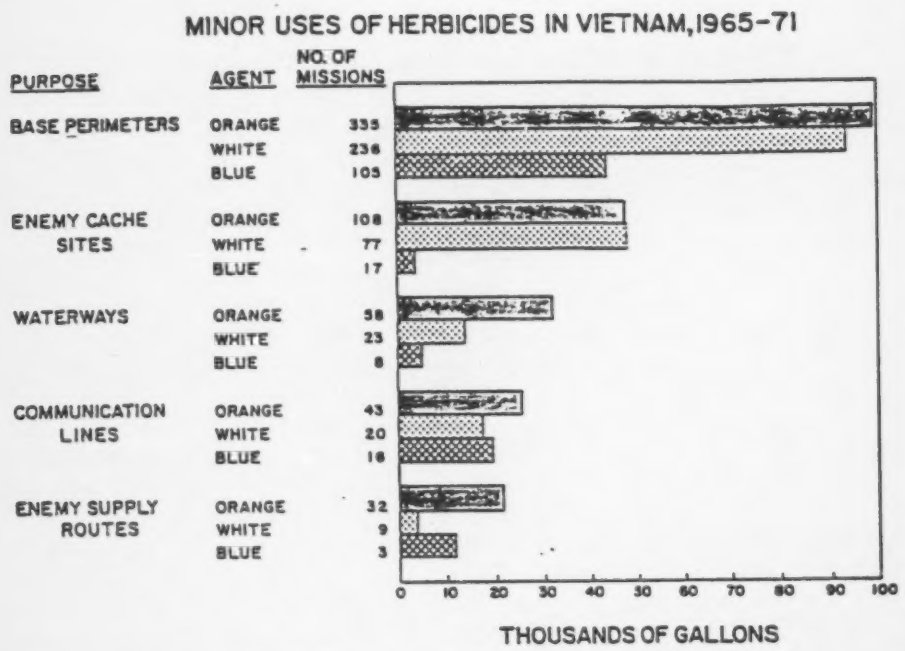

Fig. 3. Quantities of Agents Orange, White, and Blue used in five minor types of missions in South Vietnam, 1965–1971.

missions in the lowest gallonage classification (<500 gallons), and 5% of the missions dispensed less than 100 gallons.

Although herbicide use in Vietnam had begun by January, 1962, the HERBS tape covers only those spray missions conducted after June, 1965. Limited amounts (<300,000 gallons) of other dioxin-contaminated herbicides, notably Agents Pink and Purple (active ingredient 2,4,5-T), were disseminated between January, 1962, and December, 1964 [Young et al, 1978]. In that these were years before major American troop involvement, the number of U.S. servicemen exposed would be extremely small. Figure 4 shows the total herbicide usage by calendar quarter. The precipitous drop in the first quarter of 1968 coincides with the Tet Offensive. As is indicated in the figure, usage tended to be most widespread when the largest numbers of U.S. soldiers were in the field. However, the extent of direct spraying on troops has not been established, and Armed Services experts contend that spraying occurred well in advance of anticipated troop movements into target areas (G. Lathrop, personal communication).

Herbicide Exposure Probability Indexes Among 478 Vietnam Veterans

Equations 1–4 were applied to our study population. Of the 543 men sampled, 478 had sufficient information to compute exposure indices, and 303 of these judged themselves "exposed" within at least one of the categories queried in Table III. Mean scores for the various discrete and continuous scales were computed separately for men designated as "exposed" either by holding a military job with exposure or by reporting themselves to have been in contact situations as well as for the remaining

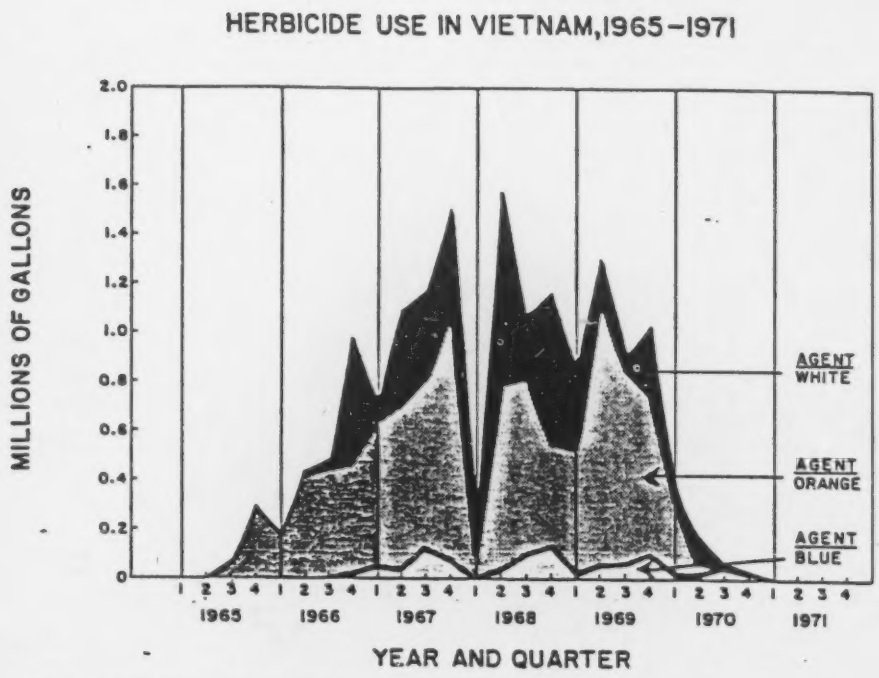

Fig. 4. Quantities of three herbicides used in South Vietnam, 1965–1971, by calendar quarter.

group of 175 men who said they did not think they were exposed and who did not indicate that they had held any of the likely exposure jobs. Results are shown in Figure 5. All six of the "exposed" groups had both C_{15} and E_3 means higher than the mean of the "unexposed" group, and all categories but one (shipping handlers, a group for which we had few observations) had more "hits within 15 km," C_{15}, than the population average for that variable.

In that a number of men belong to more than one nominally "exposed" category, the groups are not independent, so it is not meaningful to make statistical comparisons between the group means. However, the mean values of the discrete exposure index, C_{15}, as well as of the continuous indices E_1, E_2, and E_3, in exposed and unexposed groups as a whole are compared in Table IV. Mean values for E_2 and E_3 were significantly higher in the exposed compared to the unexposed: mean E_2 was 41% higher ($p < .01$) and mean E_3 was 32% higher in the exposed. Using a Mann-Whitney U test for the discrete variable C_{15}, the mean rank among the exposed was significantly higher than in the unexposed ($p < .05$).

DISCUSSION

These indexes have been developed expressly for the purpose of assigning probabilities of exposure to herbicides in epidemiological studies of large numbers of veterans and are not claimed to represent actual exposures perfectly. They are to be regarded as approximations to population exposures in the same sense that past exposures to dusts and chemicals are often estimated for workers in industries for

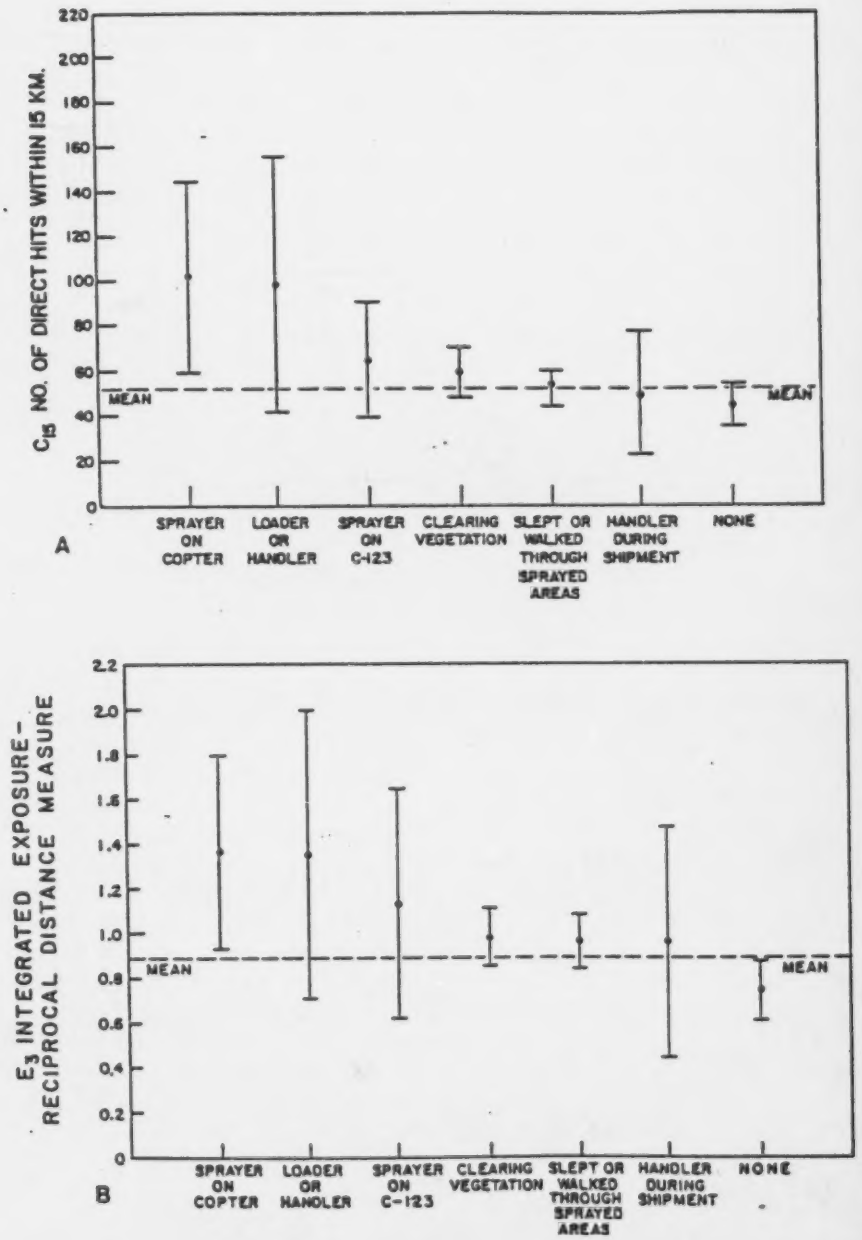

Fig. 5. A, mean discrete exposure index C_{15} computed for men with six different job categories with probable Agent Orange exposure and for men not likely to have been exposed. B, same for continuous exposure index E_3.

TABLE IV. Statistical Comparisons Between Mean Exposure Indices for Veterans Self-Described as "Exposed" and "Not Exposed" to Agent Orange

Variable	Average value of variable for veterans reporting exposure	Average value of variable for veterans not reporting exposure	p
E_1	8.94 (303)*	8.39 (175)	NS
E_2	8.25 (303)	5.85 (175)	<.01
E_3	0.98 (303)	0.74 (175)	<.05

	Mean rank	Mean rank	Mann-Whitney U	p
C_{15}	248.9 (303)	223.2 (175)	2,364.5	<.05

*Numbers of veterans are given in parentheses. NS, not significant.

which industrial hygiene measurements of past conditions are not available. As approximations, it is important to bear in mind their limitations. The HERBS tape itself is incomplete, particularly with respect to base perimeter spraying and jettisoning of some plane loads. Data on individual veterans are limited by their recall and personal records. Towns in Vietnam near where veterans were stationed are used as surrogates for actual coordinates of their unit locations. Computed exposures will thus tend to underestimate true exposures, and risk assessments will therefore be biased conservatively, ie, towards finding no association. Within these limitations, distributions of the indexes are sufficiently broad to permit comparative categorization of exposure.

As is illustrated in Figure 5 and Table IV, HERBS tape-derived exposure indices vary widely among individual troops, ranging from no exposure to a high probability of having been directly sprayed upon, and are consistent with likely exposures associated with specific military jobs and experiences in Vietnam.

It is particularly noteworthy that there is little difference in mean E_3 values for men whose self-reports indicated that they cleared vegetation or slept or walked through fields, and men who reported no exposure. We believe this to be reflective of the uncertainty and confusion that exists in the minds of many veterans about whether they were exposed to Agent Orange. Many sources of defoliation in Vietnam in addition to chemical herbicides have been documented by the National Academy of Sciences [Committee on the Effects of Herbicides in South Vietnam, 1974], such as bombing and shelling, use of Rome plows (super-bulldozers), resettlement, cutting of trees for lumber and firewood, and local agricultural practices (swidden agriculture); it is difficult to see how a soldier under the stress of combat could be expected to distinguish one cause of defoliation from another. In addition, men might have been purposefully sprayed from the air with malathion for mosquito control and might have mistaken this spraying activity as a herbicide defoliation mission (G. Lathrop, personal communication).

Our method can sort out those individuals who erroneously believe themselves to have been exposed and whose misclassification might thereby dilute any potentially observable effect in an epidemiological study. On the other hand, a self-report might

miss important sources of contact with defoliants because the soldier was unaware of previous spraying in the area. Note, for example, the statistically significant differences in E_2 and E_3 between groups in Table IV, which take into account prior spraying at a given location, compared to the lack of statistical significance of differences among values for E_1, which includes only current exposure. This demonstrates the importance of considering the residual effects of herbicide spraying encountered by troops long after the actual date of herbicide application, even though the exact rates of decay are not known.

In a previous survey of veterans [Stellman and Stellman, 1980], we recorded reports of hundreds of servicemen who had entered freshly denuded forests and who camped within defoliated areas, either in the jungle or near the perimeters of their base camps, in areas that were recently sprayed. In addition, men could have been exposed by spending time in areas long after spraying took place. Men on extended jungle patrols often swam in and drank water from streams that drained defoliated areas. The possibility of exposure from the latter source cannot be ruled out. Tissue samples from rodents, birds, fish, and reptiles trapped several years after spray tests were halted at a Florida test site for Agent Orange (Table V) contained traces of dioxin [Young et al, 1978, Chapter III, p 19].

It is precisely for these reasons that it is impossible to give credence to any health effects study in which assignment of herbicide exposure levels to individual veterans is based solely on self-reports.

We are aware, of course, of limitations associated with surveys of self-selected individuals. In health surveys, subjects can be self-selected for a variety of reasons, including concern over possible exposure to Agent Orange and concern about their own health. For this reason, any studies relating exposures to health outcomes in this population are likely to be highly biased. However, insofar as no veteran could possibly know the thousands of dates and places of missions on the tape, there can be very little selection bias in this measure. Even were a veteran to know which locations were highly publicized "hot spots," he would have to report his presence there at the right time to achieve a high score. In this study, one of our quality control procedures entails editing of all subject-reported dates at specific Vietnam locations against his

TABLE V. Levels of TCDD Found in Animals 3–8 Years After Heavy Spraying of Agent Orange at Eglin Air Force Base, Florida [Young et al, 1978]

Species	Tissue	Concentration (ppt)
Mammals		
Beachmouse	Liver	300–2400
Hispid cotton rat	Liver	< 10–210
Birds		
Meadowlark	Liver	100–1020
Mourning dove	Liver	50
Savannah sparrow	Liver	69
Fish		
Spotted sunfish	Liver	86
Mosquito fish	Whole body	12
Sailfin shiner	Whole body	12
Amphibia		
Six-lined racerunner	Muscle	360–430

dates of Southeast Asia service and overall military service. More elaborate checks against external sources are also possible, although the expense might be considerable. We believe little if any such fabrication has occurred in this study.

Therefore, we believe this to be an independent and objective source of exposure information, despite the fact that our data were elicited from participants who selected themselves to participate in our survey. Furthermore, from the wide variability of the aggregated indices for these specific locations, we infer that it would be quite difficult for a subject to deliberately fabricate a high score for himself. That is, a subject is highly unlikely to be able to identify places at random and expect that the scores for those places, restricted to the time period he served in Vietnam, would be especially high.

Because questionnaires are all self-administered, there is the usual problem of how to handle missing or obviously incorrect information. Our evaluation algorithms are biased towards minimizing exposure by truncating Vietnam location dates according to overall dates of service in Vietnam and eliminating records with no dates at all. The majority of respondents took great pains to fill out the exposure-related section and the Vietnam location and date section with care. Fewer than five questionnaires from obviously unreliable subjects were eliminated. Recent experience with another, nonself-selected group, comprising a random sample of several state membership lists of the American Legion, convinces us that veterans possess and utilize many resources to recall just where they were in Vietnam and what they did there [Stellman and Stellman, 1985].

A still more accurate exposure method would, in addition, assign different exposure values to each mission according to the actual number of gallons dispersed, the area sprayed, the rate of dispersion, and even the meteorological conditions, if these data were available. For the great majority of missions, the results obtained here would not change, because, as indicated above, the ratio of gallons to area was nearly constant. Without taking differing concentrations into account, the method is, at worst, a conservative approach to exposure estimation, because the small number of concentration outliers are concentrated in the missions carried out over the smallest acreage, hence possibly representing the most intense exposure.

There is, of course, the problem of incomplete or incorrect data on the HERBS tape itself. It is probable that we are underestimating exposure arising from backpacking and other small but intense uses of herbicides; we know that most of the missions with a substantially different gallons/area ratio from the calculated average fall in the low-gallonage category. Refinement of the method, with variations in concentration and in different types of spray missions taken into account, is currently underway. The U.S. Army is revising the 1980 HERBS tape to provide still more accurate data on backpacking missions. This new information will be incorporated into our method as soon as it becomes available.*

It might, of course, be possible for other researchers, particularly those engaged in large, government-sponsored studies, to obtain complete military records of troop movements in Vietnam, as has been attempted by Erickson et al [1984b], and to apply this or similar methods to derive still more accurate exposure information, thereby possibly eliminating many of the drawbacks associated with personal recall and use

*Note added in proof: The Army Records Management Group released a supplemental tape containing such records in September, 1985. These will be incorporated into our future reports.

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of self-administered questionnaires and approximations of concentration. On a more modest level, the method outlined in this article can be readily applied at minimal expense by the many registries and projects now being carried out by state agencies and private research groups.

The obvious next step is to examine the prevalence of adverse health conditions in relation to the values of the herbicide exposure indexes described in this paper. Such studies are now in progress. Although there will, of necessity, be shortcomings in any system attempting to classify the probability and extent of exposure to herbicides in Vietnam, because of the passage of time as well as inherent uncertainties in the actual amount of defoliant to reach the ground and come in contact with troops, the system proposed here is a mathematically defensible approach using an extensive and unique data base, the HERBS tape, which assigns probabilistic exposures to troops in an objective and impartial way.

ACKNOWLEDGMENTS

This study was made possible through the help of many individuals and institutions: Lawrence Garfinkel, American Cancer Society; John Jordan, Louise Ransom, Robert Morris, Andy Smith, Tim Smith, and Chris Iosso, National Council of Churches; Keith Snyder, Lew Milford, and Ron Simon, National Veterans Law Center, American University; Mike Gold, City University of New York Department of Veterans Affairs; Stephen Zoloth and David Kotelchuck, Hunter College of the City University of New York; John F. Sommer, Jr., The American Legion; and Richard Christian, U.S. Army Records Management Group.

This work was partially supported by U.S. Public Health Service grant NCI 5K07-CA-00730 (J.M.S.) and by a special grant from the National Council of Churches.

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DEPARTMENT OF THE ARMY
OFFICE OF THE SECRETARY OF THE ARMY
WASHINGTON, DC 20310

OFFICE, CHIEF OF
LEGISLATIVE LIAISON

10 SEP 1986

Honorable Bob Edgar
Chairman
Subcommittee on Hospitals
and Health Care
Committee on Veterans' Affairs
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

In response to your request for responses to questions for the record on the Agent Orange study, enclosed are the inserts for the record provided by Mr. Richard Christian, the Director, U.S. Army & Joint Services Environmental Support Group.

Sincerely,

SAMUEL T. BRICK, JR.
Chief Legislative Counsel

Attachments

Congressman Daschle. The specifications for determining exposure (or likelihood of exposure) are important in selecting a group of veterans "likely to be exposed." I am concerned that the standards could be set unreasonably high so that we would be precluded from selecting enough veterans to validate the study. On the other hand, if the specifications are too broad, and a large number of non-exposed veterans are included in the selection, the exposure levels will be diluted, and the results will be meaningless. What are the actual proposed specifications? While, again, I realize you are not a scientist, you are an Army historian who has a good idea of the data available and its implications. I would also appreciate your judgement on whether or not a valid, meaningful selection is possible, and if so, what the specifications for that selection might be.

Mr. Christian. We provided what was eventually approved in the original protocol for the Agent Orange study. In that protocol we agreed to reach the daily locations of 50 battalions for a two-year period. We felt that was a valid specification to provide a meaningful selection, and still do.

Mr. Daschle. In your judgement, is a valid study of the effects of Agent Orange on Vietnam veterans possible? If so, what do you think are the real problems in the way of completing that study? If not, what makes this study impossible?

Mr. Christian. Yes. If we followed the original protocol a valid study could be concluded. Some problems are as follows:

(1) Army records never were intended to serve as a basis for such a study. Our records are prepared for combat use and personnel accounting.

(2) Company elements on combat maneuvers may be and often are dispersed anywhere from five, ten, fifteen or twenty kilometers. This is especially evident in jungle warfare as conducted in Vietnam. We can locate a subelement of a company for exposure on a specific day but do not have records to show who was in that element at that time. This is a major problem in identifying the exposure for a specific soldier.

(3) An example of a good study in this area is the U.S. Air Force Ranch Hand study. If the Ranch Hand study were expanded to include possible exposures around main base camps, fire support bases, and landing zones would provide an additional coverage in providing a valid study.

Congressman Daschle. You have obviously gone through a great deal of effort to compile important information about troop movements in South Vietnam. We realize the difficulty involved, and we appreciate all your fine work. If the study were to be discontinued, what conclusions, if any, could be drawn solely from the ESG findings?

Mr. Christian. For six years ESG has painstakingly researched all the data that can be used of the 40,000 linear feet of Vietnam War records. We have done our best. There is nothing left to look at.

We have opened up all the collections the government has to use for this study. It is up to the scientist to come up with an exposure index so that we can try to fit subjects into the exposed/nonexposed categories.

ESG findings will be able to support the unit locations and time in relation to the herbicide spray missions. ESG findings can present official DOD records to support claims should they be made.

Congressman Ridge. Please identify all CDC mandated criteria that you must meet before an individual Vietnam veteran can be considered as either having a high likelihood of exposure to Agent Orange or high probability of not being exposed.

Mr. Christian. There are 10 factors involved in order for a veteran to meet eligibility for inclusion into the major Agent Orange study.

Only veterans who qualify under each factor will be evaluated for an opportunity of exposure score.

Each veteran must meet specific requirements i.e. grade; time in Vietnam; a specific job; time in a tracked unit; must only have served in specific countries; only served in the Army; only served in Vietnam during the established window, never re-enlisted; be of male sex; and have a certain military component (see Attachment A for the specific requirement on each criteria).

When a veteran fails to qualify under any one of these criteria, he is disqualified from the study. It is unknown how many men are disqualified. All we can say is that more veterans are disqualified than qualified. ESG must identify over 8,000 men in order to qualify 1,400 men for each sub group.

Congressman Ridge. Are you required to confirm a minimum of 14 day exposure to Agent Orange?

Mr. Christian. No. There never has been such a limitation.

Congressman Ridge. To date, how many men have you been able to identify that meet this minimal requirement?

Mr. Christian. We have no such minimal requirement.

Congressman Ridge. Are you also required to confirm that the individual veteran served a minimum of 180 days in country?

Mr. Christian. Yes. There is a requirement that a veteran must have spent 180 days in Vietnam, and also a requirement that a veteran must have served 180 days or more in a tracked line company.

If a veteran served one year in Vietnam, but spent 179 days or less in a tracked line company, he is disqualified. This elimination is regardless of heavy exposure while in a tracked line company.

Congressman Ridge. Were you provided a medical or scientific reason for CDC relative to this threshold of 180 days?

Mr. Christian. There is no medical or scientific basis provided, only a statistical showing that each subject be as closely alike as possible. This requirement tends to exclude soldiers in grades above E-5, who changed units (and stayed in the area), whose status was as a reserve or career status, and others.

Congressman Ridge. How many men who you identified as having a minimum 14-day exposure have been disqualified because they did not remain in country for the six months?

Mr. Christian. We never had such an exposure score as an element for searching.

Congressman Ridge. How many veterans have you identified as being exposed to Agent Orange for sevento fourteen days? Please also advise the number within this profile who met the 180-day threshold.

Mr. Christian. Again, none. In the pilot, of 727 veterans who received an exposure score, 177 scored seven or more occurrences where they were within two kilometers of a spraying mission within a six day period.

Congressman Ridge. What assumptions have been made concerning the accuracy or inaccuracy of spraying?

Mr. Christian. All documented spray records are considered accurate.

Congressman Ridge. Would your ability to identify veterans with a higher or lesser likelihood of exposure to Agent Orange be improved if the CDC imposed criteria where modified to include other areas of operations, units, rank or other related criteria?

Mr. Christian. Yes. The fewer the specifications, the easier it is to search the records. Such a search from an observance at this time would qualify more individuals.

Congressman Ridge. Were you able to identify specifically combat units who worked in areas less than 30 days after the spraying had been completed?

Mr. Christian. There has never been a 30 day exclusion from the area after a spray. No record restricting troop movements in sprayed areas for thirty days can be found. They were not supposed to be there during the spray. Our records reflect that in the Mang Yang Pass, elements of the 1st Cavalry Division and Vietnamese forces were sprayed in 1965. There also are many occurrences of troops moving into a spray area immediately after the spray flight left.

During the pilot study all seven battalions were recorded with two kilometer, three day exposure hits. This verified that all seven units operated in a spray area three days or less after an Agent Orange spray mission. Military Assistance Command Vietnam Regulation 525-1 which dictated the herbicide spray program did not specify limitations on sending troops into sprayed areas.

Air Force and ground commanders kept the troops away from the spray, as the slow-moving spray aircraft were protected by U.S. Air Force fighters from counter-ground fire. We didn't want our own troops wounded or killed by friendly fire. Seven (7) Ranch Hand Aircraft were shot down by the enemy.

Congressman Ridge. If so, were any of these units available for use in identifying veterans for the study?

Mr. Christian. ESG provided exposure opportunity scores on 727 veterans who were assigned to the seven battalions in the pilot study.

Congressman Ridge. If a veteran volunteered to be used in a study and provided information relating to time in country, area of operation, rank, etc., based upon your experience with prior individual requests for information, could you determine the likelihood of exposure and the degree of exposure and the appropriateness of use within this study?

Mr. Christian. Our records will show that a veteran was in an area where spraying occurred. Should a veteran provide identifying data, it facilitates any research required. There is no available record to show the degree of exposure.

Congressman Ridge. In your opinion, could an adequate number of veterans be identified for use in a preliminary study if information supplied by the individual veteran was made available to you for confirmation or rejection?

Mr. Christian. Yes.

Congressman Ridge. Have you made any specific recommendations to the CDC regarding changes in their identifying protocol?

Mr. Christian. Yes. Before embarking on the major Agent Orange epidemiologicalstudy, a Cohort Formation paper at Attachment B, dated January 13, 1983 was provided to CDC outlining the procedures and methodology to identify combat units and men with potential exposure to Agent Orange. During the CDC Birth Defects study, ESD provided CDC case controls with Agent Orange exposure opportunity scores. Office of Technology Assessment (OTA) and ESG refined the Agent Orange Exposure Criteria at Attachment C, dated November 6, 1984 using the Alternate Exposure Methodology for other Veterans Administration (VA) related studies.

Congressman Ridge. What documentation must you provide CDC for an individual veteran to be considered a sample cohort?

Mr. Christian. ESG must provide 143 personnel data elements on each study subject, for him to be eligible for the study.

Congressman Ridge. You mentioned during your testimony, that the CDC placed a number of limitations on who could be included in the potentially exposed cohort (such as including only those with rank E-1 through E-5).

Please list all the limitations you know of that CDC imposed on the potentially exposed cohort. For each of these limitations, please indicate, to the extent you can, whether the limitation excluded a large number of potentially exposed veterans.

Mr. Christian. CDC provided ESG a chart showing the projected losses of studysubjects for each criteria for sub group #1 (see Attachment D).

Originally, CDC projected 8,670 studysubjects for each sub group. About 3,096 (36%) of the study subjects are disqualified for grade, multiple enlistment, service tours other than accepted countries (Germany, Korea, Vietnam and the United States), service dates, sex, less than 6 months foreign service, and not in a tracked unit.

Next, 1,052 study subjects (12%) are eliminated because they served all their time in a Headquarters Company.

Another 2,378 study subjects (27%) are disqualified because the veterans served some time before or after the proposed study window (January 67 - December 68).

The next disqualifier eliminated 369 veterans (4%) from the study because they served time in a unit that was not being tracked by ESG.

Finally, CDC eliminated 342 (4%) individuals because they did not serve at least 180 days or more in a tracked line company.

In the final analysis, only 17% (1433) of the study subjects are qualified for each sub group.

Using the CDC projection covering a 19 month period (June 1985 to January 1987), ESG would need to identify 165,000 veterans to qualify 27,000 study subjects. The protocol originally required only 6,000 study subjects for the high exposed, low exposed and not exposed cohorts. Presently, the not exposed cohort has been eliminated from the study. This would require our organization to qualify 12,000 study subjects. To date, we have sent CDC 143 data elements on over 16,000 qualified study subjects.

10 Factors a Veteran Must Meet

for Inclusion in the Agent Orange

Epidemiological Study

1. Rank: A veteran must be E-1 through E-5. All E-6 and above are disqualified. If a veteran was an E-5 while in Vietnam and was promoted at his next assignment in the States, he is disqualified. Regardless of his known exposure. All Officers are disqualified. If a veteran was an E-5 or below while in Vietnam and was Commissioned into the Regular Army, he is disqualified, regardless of his known exposure.

2. Time In Vietnam: A veteran must spend 180 days in Vietnam. If a veteran spent 179 days or less in Vietnam, and possibly experienced high numbers of exposure, he is disqualified from the study.

3. Specific Job: If a veteran has a Military Occupational Specialty (MOS) of 09B or 57A10 he is disqualified from the study. All other MOS's qualify for the study.

4. Time In a Tracked Unit: A veteran must spend 180 days in a tracked line company (A,B,C,D,E). If a veteran spent 1 year in Vietnam, but only spent 179 days or less in a line company, regardless of his number of exposures in the line company, he is disqualified. The number of days spent in a Headquarters Company, convalescence in a hospital or time spent in an untracked unit are not counted, as the veteran's total time in Vietnam (even if the veteran had a high exposure score during his time in the line company (If it did not total 180 days or more), he is disqualified). If a veteran spent any time in an untracked unit, regardless of duration, he is disqualified. (This makes sense for the non exposed cohort but, should not apply if the veteran totaled high numbers of exposure when he was in a tracked unit).

5. Served In Specific Countries: Veterans could only serve in, or a combination of tours, in either CONUS, Vietnam, Korea or Germany to qualify for the study (Example: We know the veterans exposure score but because he also served a tour in France or, Japan, Phillipines, Thailand etc...he is disqualified).

6. Army Service Only: If a veteran served in the Marine Corps, Navy, or Air Force for more than 30 days he is disqualified from the study even if he may have been exposed to Agent Orange.

7. Served in Vietnam 1 October 1966 to 31 March 1969: A Veteran who entered Vietnam one day before 1 October 1966 or was still in country one day after 31 March 1969 is disqualified, even if the veteran experienced high numbers of exposure during the study window period. This makes sense for the non-exposure cohort, but not the exposed cohort.

8. Never Re-Enlisted: If a veteran re-enlisted; he is disqualified, even if we knew his units exact location for every day he was in Vietnam and we knew his exact exposure score (high or low).

9. Must be MALE: Females are disqualified.

10. Military Component: Only RA (Regular Army) and US (Draftees) are eligible for the study. If a veteran is NG (National Guard) or a Reservist, he is disqualified, regardless of exposure.

January 13, 1983 FINAL DRAFT

COHORT FORMATION FOR EPIDEMIOLOGICAL STUDY OF

HEALTH EFFECTS OF AGENT ORANGE

1. Reasons for Cohort Formation

To determine if exposure to Agent Orange, a phenoxy herbicide used in Vietnam, affected the health of American military personnel, the physical and mental health of a group or cohort of exposed veterans must be compared with the health of a cohort of relatively unexposed veterans. If such groups can be accurately identified, a cohort or follow-up (historical prospective) study design is both possible and desirable. For greatest validity, the two cohorts should be as similar as possible except for contact of their members with Agent Orange.

2. Problems of Cohort Formation

Estimating exposure is the crucial step in forming the exposed and non-exposed cohorts that are the keystone of this study design. No records were kept of an individual's exposure to Agent Orange, however, because it was believed to be a safe herbicide. Records do exist, however, for most of the dates and places where the herbicide was heavily used and separate records exist for the daily location of many military units. It is possible also to indicate the dates each man was with his unit by reconstructing rosters of the men in those units with adequate records.

From these data it might be possible to estimate the extent of exposure for many individuals. The likelihood and intensity of exposure could be evaluated using the type and time of exposure and the distance from the point of herbicide application. The "type of exposure" includes such experiences as entry into an area recently sprayed by an aircraft, presence in a base camp during perimeter spraying, or being nearby when a plane dumped or jettisoned its load of herbicide in an emergency. The "time of exposure" refers to the period between the herbicide application and the unit's presence in the area. The "distance" refers to the proximity of the unit to the point of application. ATCH # B

When enough information is available to "weight" the amount of exposure under various circumstances, the exposure at each episode can be estimated and the weighted values for each individual can be summed to give an "index of exposure". In an initial retrieval test of cohort selection, such an index can be applied to determine whether a heavily exposed and a non-exposed or minimally exposed cohort can be defined. [If separation is obtained by criteria acceptable to the scientific community as well as knowledgeable veterans' representatives, the essential cohort selection will have been shown to be feasible.]

3. Development of Exposure Cohorts

Of prime importance to a proposed epidemiologic study of the effect of exposure to Agent Orange on the health status of Vietnam veterans will be a clear, thorough statement of the process used to identify study subjects. The procedure currently recommended by the Army Agent Orange Task Force (AAOTF) has been designed to make this selection feasible, efficient and as unbiased as possible. To minimize the very large number of records to be reviewed and data to be entered a multistage selection process is used. The basic selection or "sampling" frame will be the military unit which will be characterized as "exposed" or "not exposed". Individuals will then be identified from selected units and further studied to assure their experience is correctly represented by the unit's classification.

The retrieval test phase of this study will determine whether adequate cohorts of exposed and non-exposed can be defined. To accomplish this an audit trail will be maintained of all units identified, the proportion selected and the basis for exclusion of the non-selected individuals or units. Thus the retrieval test will also perfect the selection process to be used during the full study.

For a meaningful comparison of outcomes among subjects "exposed" and "unexposed" to Agent Orange, cohorts should be as similar as possible in other aspects of the Vietnam experience. Thus, units should be stratified to reduce heterogenicity. It should be sufficient to select exposed and unexposed units from the same branch of service, in a similar type of unit, and operating in the same Corps. If possible, similar terrain would be a useful fourth criteria. In the first step in finding unexposed units, candidates are selected from among those that were operating beyond the reasonable maximum drift for Ranchhand spraying. It will be necessary to evaluate other potential exposures (e.g. perimeter spraying, dumps, etc.) for a final classification into exposed or unexposed units.

The availability, completeness and accuracy of the various record systems is unknown at present and this will be studied during the retrieval test. However, the procedural guidelines or selection algorithm used by the AAOTF is to a large part based on assumptions about these records. This increases the likelihood the AAOTF staff will encounter unexpected variations. If this requires AAOTF staff to make eligibility decisions on units or individuals not anticipated in the algorithm, a brief anecdotal record of the nature of the problem and the convention adapted to solve it is most important. This will facilitate an evaluation of the cohort selection process for potential selection bias during the retrieval test and will determine the feasibility of the proposed epidemiological study.

The following procedures are for selection of Vietnam service subjects with high and low likelihood of exposure to Agent Orange or other herbicides while in Vietnam and do not include the selection of a non-Vietnam cohort. The outlined steps have been included in the guidelines supplied by the AAOTF. The documentation requirements provide information to evaluate the feasibility of identifying adequate cohorts for the full-scale study.

3.

Specific attention is directed to the concept of "tracking time". An individual need only be in an exposed unit for enough "contacts" to qualify as heavily exposed. Therefore the tracking time for these units would be just enough months to generate an adequate number of personnel exposed. They may be followed for a shorter period. On the other hand, the non-exposed or minimally exposed individual must be followed for his entire tour. An individual typically served exactly 1 year and could enter the unit throughout the year. Therefore, a non-exposed unit's tracking time must be more than 1 year to establish this category. How much longer again is determined by the number of non-exposed needed.

4. Procedure to Develop Cohorts

I. Prepare maps of Vietnam with Ranchhand spray tracks (both defoliation and crop) for the period 1967-1968 (this has already been provided).

II. Define geographically homogeneous areas with known ground troop activity with and without Ranchhand tracks during the 2-year period.

This is the first step and defines areas which might be selected. The rationale for choosing selected areas must include areas with and without Ranchhand tracks, similar location (and if possible terrain), and the presence of ground troops. If possible, all four Corps of RVN should be represented.

III. a. Obtain appropriate station lists for each area selected.

b. Determine potentially eligible units which were operating in selected areas during the 2-year period.

All units identified from station lists are potentially eligible.

IV. Develop "enhanced" HERBS Tape by including information from herbicide applications not identified from Ranchhand missions. This will include perimeter sprayings, road clearings, helicopter missions, aborts and other identifiable applications. It should not be necessary to do more than those areas previously identified in Step II above, but, it will be necessary to include an adequate tracking time based on the unit's exposure status in those areas to be studied.

V. Determine availability and completeness of all eligible units' records of movement.

A necessary part of evaluating the reliability of exposure estimates will be the assessment of estimated completeness of the available records for herbicide applications. Documentation of completeness will assist in this effort, especially the number and type of obvious errors and suspected inaccuracies.

VI. a. Select units to be recorded as to daily movements.

This is a crucial step, and documentation of how and why a unit (or units) were selected should include the eligibility of all units which were potentially eligible and might have been selected. The potential for the selection of adequate numbers of units (or subjects) for a full scale study may depend on records' completeness and availability at this step. Obviously only a small subsample (one or two areas perhaps) can be done in the retrieval test.

b. Record to machine readable format the daily location coordinates for selected units for the entire tracking time.

VII. a. Match daily location coordinates of selected units via computer with the "enhanced" HERBS Tapes to determine the number and type of "contacts" sustained by each eligible unit between January 1, 1967 and December 31, 1968. Each "contact" will be defined and recorded according to all of the following four parameters for each unit:

i) Date

ii) Type of application (Ranchhand, Helicopter, Aborts, Ground, incidents)

iii) Time in days since application (3 days or less)

iv) Distance from application site in km (2 km or less)

b. List the "contacts" for each unit matched and the weighted score.

An Appendix illustrating an index or weighting scheme is in preparation. While it may not be possible to quantify exposure with certainty, at least a weighting rule may be developed to classify high and low exposure units. An additional category in both time and distance parameters is intended to provide a buffer between exposure and non-exposure. A "contact" in this time-distance zone will not constitute an additional exposure in otherwise exposed units but will be considered a possible exposure in units to be classed as low-likelihood-of-exposure. Thus, "low-likelihood-of-exposure" units will not be considered to have been exposed unless they have been within 1 km within 15 days or within 5 km within 1 day of a Ranchhand application target (if the retrieval test shows this is feasible).

VIII. Select high and low likelihood of exposure units.

This step will depend on selection via the weighting system developed for the previous step as well as the results from the retrieval test. The rationale for selection will be indicated and should include other criteria for the type of units chosen as well as herbicide exposure. Depending on the results of Step VII, it may be possible to identify "low-likelihood-of-exposure" units with no "contacts" of any kind. If this is the case, then a specific weighting system to discriminate between high and low exposed units will not be crucial for selection. "High likelihood of exposure" units can then be selected from among those units with at least several "contacts" of various kinds (exclusive of buffer zone contacts).

IX. a. Obtain daily morning reports for an adequate tracking time during the period January 1, 1967 to December 31, 1968, for each unit selected in the previous step.

b. Track individuals through service with their respective units during this time period and record presence on "contact" days for their unit.

Some criteria for eligibility will have to be developed and documented, including the minimum number and quality of individual's "contact" days, reliability of records for identification of individuals during this step, and their minimum length of assignment to the unit.

X. a. Obtain service records for selected individuals and verify service information obtained via morning reports.

b. Record personal information from service record and include location of medical record for each selected individual.

At this step, it may be desirable to retain the individual's identification as either exposed or unexposed during the period covered in these procedures. This should enable closer matching of the two groups based on individual characteristics obtained from the service record. It will be necessary to identify multiple tours of duty in Vietnam and perhaps other criteria pertaining to military service which will influence an individual's final selection into either of the Vietnam service cohorts. Documentation of these inclusions and exclusions will be necessary in order to assess bias in the final selection.

Although most of these procedures are included in the guidelines supplied by the AAOTF, they are detailed here to identify the steps and type of documentation which will be useful in the evaluation of the exposure index and determination of the feasibility of selecting exposed and unexposed cohorts for the full scale study. Systematic departures from the procedures outlined here which may be necessary for the inclusion of subjects from each of the four branches of military service should be included in the documentation.

DRAFT

6 NOV 1984

ATTACHMENT "C"

AGENT ORANGE EXPOSURE CRITERIA
For Use With
The Alternative Exposure Methodology

1. Exposure Opportunity Extremely Likely:

   A. U.S. Army Chemical unit personnel and Army Aviation personnel involved in herbicide spray operations

   B. All personnel who were within 2 kilometers or less distance from a Ranch Hand Agent Orange Herbicide mission track including aborted Agent Orange dumps within a 72 hour period immediately after the spraying or dump.

   C. Documented ground handler of herbicide drums.

   D. All personnel who worked on Ranch Hand herbicide leaks (e.g. base civil engineer personnel) and herbicide leak clean up operations.

   E. U.S. Air Force Ranch Hand personnel

   F. All personnel who were within 2 kilometers or less distance from either a helicopter and/or perimeter/ground spraying of Agent Orange and within a 72 hour period immediately after the spraying.

2. Exposure Opportunity Extremely Unlikely:

   A. Personnel operating offshore and the ship does not have its home port in Vietnam (does not include riverine personnel).

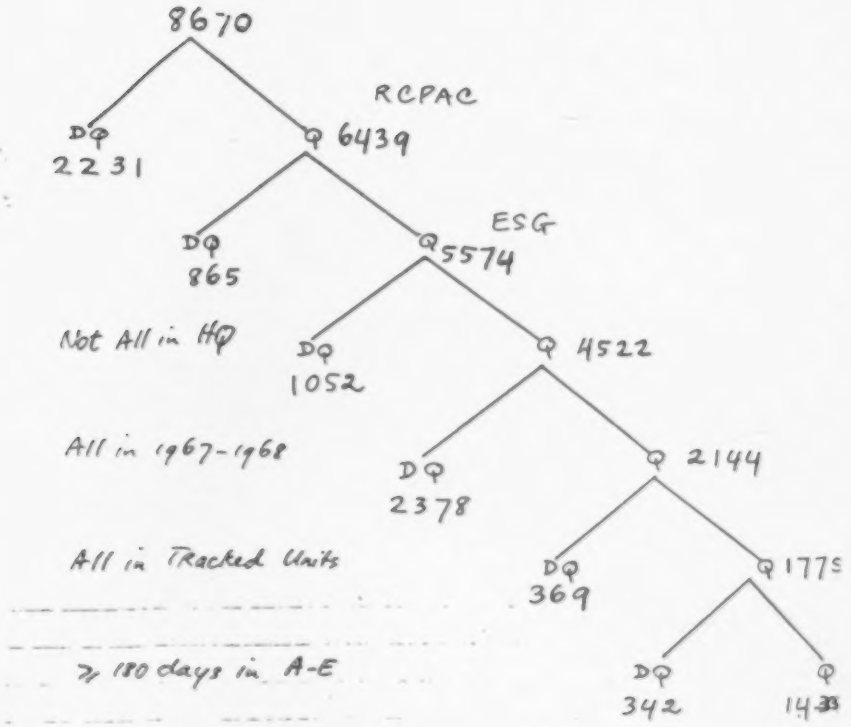
   B. Marine Corps, Navy, Air Force pilots and crewmembers (Non-Ranch Handers) who were not based in Vietnam.

   C. All other personnel located or operating beyond a 2 kilometer distance of a Ranch Hand spray mission track or aborted Agent Orange dump within the 72 hour period after the spraying or dump or at a later time.

   D. All personnel who were located or operating beyond a 2 kilometer distance from either a helicopter and/or perimeter/ground spraying of Agent Orange within the 72 hour period following the spraying or at a later time.

DRAFT

Projection Based on Group 1 Rates



ATCH D

Number of Men Abstracted by ESO and Ltr/c
Number Qualifying, By Battalion (Total = 40)
Fiel 3 Corps

DRAFT

Battalion	Total N	Total %[a]	Qualifying N	Qualifying %[b]
1	1417	19.0	444	31.3
2	1244	16.7	358	28.8
3	1046	14.0	254	24.3
4	646	8.7	138	21.4
5	348	4.7	98	28.2
6	185	2.5	64	34.6
8	91	1.2	31	34.1
10	496	6.6	162	32.7
13	48	0.6	13	27.1
16	577	7.7	142	24.6
18	137	1.8	53	38.7
21	86	1.2	23	26.7
72	44	0.6	5	11.4
32	42	0.6	5	11.9
41	40	0.5	14	35.0
42	42	0.6	13	31.0
52	44	0.6	23	52.3

[a] Percent of 7463 abstracted

[b] Percent of those abstracted for that battalion

Numbers and Percents of Men Excluded and Qualified, by Reason and Type of Battalion of First Service
Groups 1-3 combined

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Battalion Type	No combat		outside 67-68		withdrawn battalion		2 180 days combat		Eligible		Total	
	N	%	N	%	N	%	N	%	N	%	N	%
Infantry	1002	20.2	2085	42.1	206	4.2	293	5.9	1371	27.7	4957	66.4
Artillery	278	24.2	443	38.6	39	3.4	40	3.5	349	30.4	1149	15.4
Cavalry	81	15.5	223	42.6	17	3.2	34	6.5	168	32.1	523	7.0
Armor	118	33.9	121	34.5	1	0.3	10	2.9	98	28.2	348	4.7
Engineers	2	16.7	6	50.0	0	0.0	0	0.0	4	33.3	12	0.2
Other	123	25.9	55	11.6	219	46.2	77	16.2	0	0.0	474	6.4
All	1604	21.5	~~3034~~ 2913	40.6	~~458~~ 439	6.1	377	5.0	1990	26.7	7463	100

First battalion of service missing for 10 men.
Percent is of men starting in that type of battalion, except for total.

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TABLE 1

	Group 1		Group 2		Group 3		Total	
	N	%	N	%	N	%	N	%
Total	4386	100	2088	100	996	100	7470	100
Not All in HQ	3558		1588		741		5887	79
All 67-68	1687		731		405		2823	38
All Tracked Units	1397		645		323		2365	32
≥ 180 days in A-E	1128	26	567	27	293	29	1988	27

TABLE 2

. All Oct 1, 1966 to Mar. 31, 1969	2362		1019		595		3976	53
. All Tracked Units	1928		880		485		3293	44
. ≥ 180 days in A-E	1583	36	774	37	443	44	2800	38

TABLE 3

. All Jan. 1, 1967 to June 30, 1969	2774		980		505		4259	57
. All Tracked Units	2247		846		407		3500	47
. ≥ 180 days in A-E	1877	43	737	35	376	38	2990	40

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TABLE 1

	Group 1		Group 2		Group 3		Total	
	N	%	N	%	N	%	N	%
Total	4386	100	2088	100	996	100	7470	100
Not All in HQ	3558		1588		741		5887	79
All 11/1/67-3/31/69	2323		872		470		3665	49
All Tracked Units	1899		753		377		3029	41
≥ 180 days in A-E	1562	36	658	32	346	35	2566	34

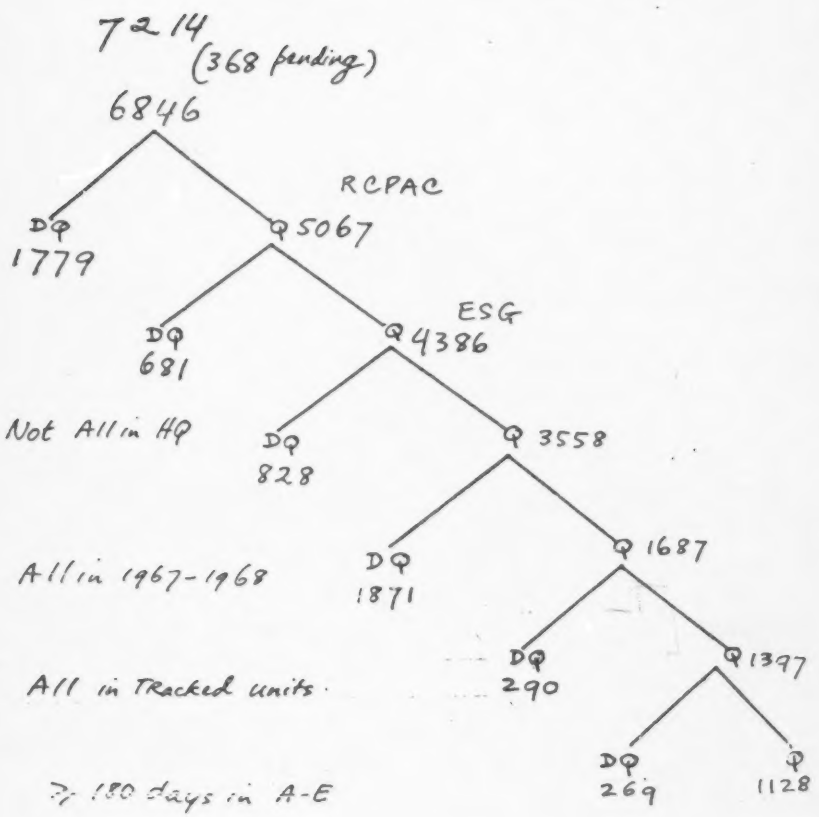
TABLE 2

• All Jan 1, 1967 to Apr. 30, 1969	2523		905		493		3921	52
• All Tracked Units	2040		779		398		3217	43
≥ 180 days in A-E	1689	39	681	33	367	37	2737	37

TABLE 3

• ALL Jan 1, 1967 to May. 31, 1969	2665		956		502		4123	55
All Tracked Units	2195		825		405		3385	45
≥ 180 days in A-E	1794	41	722	35	374	38	2890	39

GROUP 1 DRAFT



QUESTION OF CHAIRMAN EDGAR TO THE OFFICE OF TECHNOLOGY ASSESSMENT:

Please provide a chronological record and explanation of your activities in regard to oversight of the Centers for Disease Control Agent Orange Study as required by Public Law 96-151.

Since the passage of PL 96-151, OTA staff have carried out the activities specified in the law--reviewing study protocols and monitoring the conduct of studies--and have also participated in a large number of related activities. OTA has been an observer on the full Agent Orange Working Group (AOWG) until its reshaping in 1985, and on the AOWG Science Panel, an activity that continues to the present. OTA staff have established good working relationships with the relevant Executive Branch agencies, including various offices within DHHS, VA, DOD, and EPA.

Over the years, we have reviewed, analysed, and provided detailed comments to the Veterans' Affairs Committees on numerous scientific studies and proposals relating to dioxin, Agent Orange, herbicides, and related industrial exposures. Some examples include: the reports from the Air Force Ranch Hand Study; the Australian studies of Vietnam veterans; CDC's study of the risk of Vietnam veterans fathering children with birth defects; the VA's proposed study of identical twins (including a meeting of OTA's Advisory Panel); proposals to carry out research in Vietnam; several State studies of mortality among Vietnam veterans; the American Legion/Columbia University study of Vietnam veterans; and a study of mortality among veterans related to draft-eligibility from the 1970-72 draft lottery.

Highlights of OTA's activities related specifically to the mandated studies are summarized in the chronology below. In addition to these specific points, OTA receives formal quarterly reports from CDC describing progress in each study, communicates directly with the CDC Agent Orange Projects staff, and answers numerous written and telephone inquiries from Congressional staff, members of the academic community, and the public.

1979

December	Passage of PL 96-151 assigning the OTA Director responsibility to review and approve the study protocol within 180 days after passage of the Act. If the OTA Director had not approved the plan by then, he was periodically to report reasons for the lack of approval to Congress

1980

[February-June	VA issues Request for Proposals to develop study protocol (February); VA is sued by the National Veterans Law Center (May); Judge Green of DC District Federal Court asks GAO for ruling on legal protest (June)][1]
August	OTA begins making periodic reports to the Congressional committees about reasons it has not approved a study protocol.

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1. Important events not directly involving OTA appear in brackets.

	At that time, VA expected to issue contract in September. Subsequent reports kept committees informed of continuing legal delays
1981	
[February-May	GAO finds in favor of VA (February); VA contacts bidders, reconstitutes selection board to examine revised bids (Feb.-April); VA awards contract to develop protocol to UCLA School of Public Health (May)]
May	OTA assembles Agent Orange Advisory Panel, which continues to function to the present with few changes in membership
August-September	OTA receives draft protocol for a group of Agent Orange studies from UCLA; OTA Agent Orange September Advisory Panel meets; OTA submits 50-page review with detailed comments and suggestions for the investigators to incorporate into a revised protocol
November	OTA presents testimony at Senate Veterans' Affairs Committee hearing on Agent Orange study progress
1982	
January-March	OTA receives new draft Agent Orange study protocol from UCLA, revised in accordance with OTA's and other reviewers' suggestions; OTA convenes its Advisory Panel, gives provisional approval; final approval pending further minor revision
June	OTA sends letter to committees approving protocol
September	House of Representatives Veterans' Affairs Committee hearing on lack of VA progress in arranging to implement the study; OTA letter to committees informing them of specific problems at VA related to lack of progress; letter signed by 101 Congressmen and Senate Veterans' Affairs Committee letter to VA suggesting that VA hand control of study to CDC
1983	
[January	Agreement between CDC and VA to transfer control of study]
February-March	CDC produces brief outline of 2 proposed studies: Agent Orange and Vietnam Experience; OTA Advisory Panel meets; OTA submits review with comments and suggestions to congressional committees and CDC
June-July	CDC produces draft protocols for 3 studies: Agent Orange, Vietnam Experience, and Selected Cancers; OTA favorably reviews the general approaches proposed, but withholds judgment on exposure classification; OTA testifies at Senate Veterans' Affairs Committee Agent Orange hearing

1984

January-February	OTA receives revised CDC protocols and approves Vietnam Experience and Selected Cancers studies unconditionally; notes that exposure assessment for Agent Orange study still to be worked out

1985

February-April	CDC transmits first report about Agent Orange exposure assessment to OTA; OTA holds Advisory Panel meeting; rejects proposal as a basis for the study, agreeing with CDC to assess progress in six months; OTA staff meet with Environmental Support Group, arrange for CDC/ESG meeting to discuss problems relating to exposure and interagency cooperation
September	OTA writes to committees expressing concern that CDC had not communicated to OTA about progress in exposure assessment; OTA presents testimony at House Committee on Veterans' Affairs hearing on CDC Birth Defects Study
November-December	CDC transmits documents; OTA holds Advisory Panel meeting and submits critical review to committees; OTA recommends CDC not initiate interviews until exposure issues are resolved

1986

[January	CDC informs committees of plans to proceed with interviews in January and submit a revised protocol for a March-April 1986 review; committees write to DHHS stating their wish that the interviews not proceed until a protocol is approved; CDC postpones interview plans]
[April-June	A Subpanel on Exposure is formed under the aegis of the AOWG Science Panel; through Science Panel, OTA participates in formulating plan for pilot study of exposure assessment methods and related issues; pilot study is completed, reviewed by Science Panel, including OTA, and transmitted to AOWG]
July	OTA presents testimony at House Veterans' Affairs committee Agent Orange hearing

FOLLOW-UP QUESTIONS TO MS. HELLEN GELBAND, DIRECTOR OF SPECIAL PROJECTS, HEALTH PROGRAM, AND AGENT ORANGE PROJECT DIRECTOR, OFFICE OF TECHNOLOGY ASSESSMENT, FROM CONGRESSMAN TOM DASCHLE:

1) CDC has proposed a new blood test for detecting the level of dioxin in the body. Since the scientific validity of the test is still to be determined, I am interested in whether or not there are scientifically valid methods of tracing dioxin in the body already available to us? How has dioxin been traced in the people involved in the Times Beach and Seveso accidents and in other studies? Would any of these methods be useful to this study?

Currently, the best method for measuring body burden of dioxin is through analysis of adipose tissue, otherwise known as fat, where dioxin is stored. There have also been analyses of dioxin in organs obtained at autopsy, e.g. the liver, and measurements made in human breastmilk. As an indicator of exposures in the past, however, fat seems to be the best tissue to study. Because of the success of fat analyses, researchers began looking for dioxin in the fat component of blood plasma. The levels of dioxin in blood are much lower--by a factor of about 100, according to CDC data--than are levels in body fat. Improved analytic instruments and procedures now allow relatively accurate detection at those levels, a feat not possible just a few years ago.

There is little doubt that dioxin can be accurately measured at low levels in human fat, and according to recent reports, that probably is true for blood as well. The relationship of body burden to exposure is not so clear, but some generalizations can be drawn from the available data. First, relatively few dioxin determinations in fat have been made worldwide, on the order of a few hundred, in a small number of laboratories. Although some samples have undetectable levels of 2,3,7.8-TCDD, nearly all have some dioxin, and this is increasingly the case as detection limits have improved. In CDC's dioxin study in Missouri, for instance, the "unexposed" controls had adipose tissue levels ranging up to 20 parts per trillion (ppt) or so. In that study, 39 "exposed" individuals were tested. Half of those people had levels within the background range of the controls. Two people had levels between 700 ppt and 800 ppt, one between 500 ppt and 600 ppt, three between 100 ppt and 200 ppt, and the rest less than 60 ppt. These levels are similar to other studies of "exposed" and "control" groups, with a few very high values in the exposed, many exposed without unusually high fat levels, and generally low levels in unexposed.

If one can generalize from the available data, I think the thrust is that if a high dioxin level is found in an individual, it is explainable by some known, identifiable, occupational or environmental intense exposure. Looking at the obverse, however, it is <u>not</u> true that all people with what appear to have been the same intense exposures will also have high dioxin levels. In fact, many have levels in the background range. The reasons for these individual variations are not known.

The highest value for human tissue of which I am aware, more than 1800 ppt, is from a Seveso woman who died from a preexisting cancer some days after the ICMESA plant explosion, and whose tissues were sampled at autopsy. As far as I know, no other adipose tissue tests were done at Seveso and levels of "exposure" were assessed according to where people lived and worked in relation to the plant and the dioxin-laden outfall from the explosion.

There are practical difficulties with performing adipose tissue analyses. First, a surgical procedure, requiring hospitalization and time for recovery, is required to remove enough fat for the analysis; this is not an acceptable procedure to many people. In addition, there are currently few laboratories in the world capable of performing the analysis, and it is expensive. The blood test has a clear advantage in ease of collecting the sample. To the extent that it correlates with the levels in fat, whatever inferences could be drawn from fat analyses can be drawn from blood analyses. At present, however, laboratory capability to perform the blood analysis is even more limited than capability for fat analysis, and the procedure is still expensive. The blood analysis, however, offers the best hope for determining body burden of dioxin in a practical way.

(Enviro-Health Systems, Inc,. of Richardson, Texas, claims to have the approval of the U.S. Department of Health, under the federal Clinical Laboratories Improvements Act, to conduct simple, inexpensive ($135 per person) tests that trace levels of 2,4,-D and 2,4,5-T in the body. Is this true? Are these tests applicable to this study? I have information on this lab if you need it.)

Enviro-Health Systems, Inc. does test for 2,4-D and 2,4,5-T in urine. The purpose of those tests is largely to detect recent exposures to the herbicides themselves, which, unlike the 2,3,7,8-TCDD contaminant, is cleared from the body relatively quickly. This does not appear to be a feasible approach to estimate Agent Orange exposure 15 years or more in the past. The company is also interested in dioxin analyses, however, and judging from brief communication with them, they are developing ideas for new approaches to blood testing which might be of value in screening for dioxins in general. I will pass the information I have on this company to CDC and to the Agent Orange Working Group Science Panel for their consideration.

2) What about the possible long-term effects of dioxin? How does the new finding that the half-life of dioxin could be as long as ten years affect the study? Also, since it has been more than ten years since veterans returned from Vietnam, what are the possibility that dioxin that could have been in the body and caused adverse effects but would now be untraceable?

The best available estimate for the half-life of dioxin <u>in the body</u>, to my knowledge, is about 5 years. That estimate is based on scanty data, including one scientist who injected himself with radioactive dioxin and a short time later compared the level of radioactivity with the initial level. Based on the small decrease in activity, he calculated a half-life of 5 years. There is little information about the range of variability among human beings in their uptake of dioxin and in the way it behaves once in the body. Reliable fat analyses have been done for about the past five years, however, and it might be possible to gather additional information by going back to some of the people sampled at that time who have had no significant intervening exposure to 2,3,7.8-TCDD and asking them to again donate a fat sample. The previous and current levels could then be compared.

The concept of "half-life" is based on the idea that the amount of a substance that disappears or is used up is relative to the total amount of the material present in the first place. It is a concept that derives largely from radioactivity, which declines in just such a fashion. It has come to be used widely, and while the biological processes it sometimes describes may not entirely fit the half-life model, it is a convenient way to express the processes of decay or removal of a substance. The important point is that after a given time period, e.g. 5 years, <u>half</u> the original amount remains; after another 5 years, half of the remainder (i.e., one-quarter of the original) remains; after 5 more years, one-eighth of the original amount remains. In the case of dioxin, if an individual started out with a very high level, assuming a 5-year half-life, about 6 percent would still be present after 20 years, roughly the period that has elapsed since Vietnam exposures. That would probably be sufficient to distinguish a highly exposed individual from one with only background exposures. If the pattern of decline does not, in fact, approximate the half-life model, the amount remaining might be more or less.

It is, of course, of concern that dioxin remains in the body for such long periods of time, and the possibility exists that the total risk of adverse effects, if any, may increase with the amount of time that dioxin persists.

3) Do you think a valid study is possible? If so, what needs to be done to facilitate that outcome? If not, what makes the study impossible? What is your recommendation for the future of the study?

First, let me state what I see as the major obstacle to carrying out an Agent Orange study: based on the information that can be abstracted from military records, it appears that few ground troops had the opportunity for heavy exposure to Agent Orange in Vietnam. The prerequisite for any cohort study of chemical exposure is the identification of a group of exposed and a group of similar but unexposed individuals. If exposures do not differ or if there is a great deal of misclassification, the study results are uninterpretable in determining the effects of the chemical. In my view, that is where the study now stands.

I believe that the Ranch Hand study, despite its small size, is the best possible study of a population exposed to Agent Orange. One of the reasons for pressing to do a study of ground troops is that it was thought that the exposures of ground troops might have been greater because of being in contact with Agent Orange-contaminated foliage or soil without the chance to bathe, and the possibility that they may have drunk Agent Orange-contaminated water while out in the field. This contrasts with the experience of Ranch Handers who had a more typical "occupational" exposure. The recent report of the New Jersey Agent Orange Commission provides at least some evidence that Ranch Handers did receive significant exposure, based on dioxin levels in their blood and fat. Unfortunately, that study does nothing to add to the knowledge base about ground troops, which is the problem we face.

I think that CDC's general approach in trying to use the dioxin in blood assay is a reasonable one and OTA, with the help of our Agent Orange Advisory Panel, will be reviewing the details of that plan. I hope that effort corroborates the current state of knowledge that ground troops were, by and large, little exposed to Agent Orange. If that is the case, there is no way to carry out a meaningful Agent Orange study, and more importantly, no reason to do so. I have no doubt that there are individuals--some Ranch Handers, those in the chemical corps, people who sprayed base perimeters, and others-- who had significant exposures, and judgments about whether their exposures caused adverse health effects should be based on the entire scientific literature concerning the health effects of herbicides and dioxin. While that literature is not entirely consistent and does not admit of simple interpretations, there are still studies of heavily exposed groups under way, and more information will be coming in over the next few years. Carrying out a study of minimally-exposed veterans will not provide answers for those who were heavily exposed, but it is possible to generalize results from a heavily exposed group to a less-exposed group.

QUESTIONS OF CONGRESSMAN TOM RIDGE FOR: HELLEN GELBAND, Health Analyst, Office of Technology Assessment

1. In your testimony you note that the study hinges on an ability to assemble groups of men who are different with respect to exposure, but similar in as many other ways as possible. OTA has concluded that none of the CDC protocols to corroborate toxin exposure have been acceptable. Has OTA made any inquiries of other countries or private corporations, domestic or foreign, to determine whether or not other protocols may be available for testing? If so, please identify and explain.

I am happy for the opportunity to clarify our position on identifying an exposed cohort. OTA did not find fault with the general approach of CDC to classifying exposure using the military records. This general approach consisted of assigning a weighted value for exposure each time a man was near an Agent Orange spray in space and time, and accumulating those values in an overall exposure rating. It was thought that a large number of men would have spent weeks or months in freshly sprayed areas. Our concern that the study was foundering came when we saw CDC's data showing that, in fact, very few ground troops had such exposures. We did not feel that the "exposed" group was very different from the "unexposed" group; a study comparing those two groups would tell us nothing about the effects of Agent Orange, if any, in people who really were heavily exposed, and I have no doubt that some relatively small number of men were heavily exposed.

OTA has kept abreast of dioxin and herbicide-related studies around the world, though we have not solicited ideas for Agent Orange study protocols. I don't believe that the main problem now being experienced with the Agent Orange study--the inability to identify a large group of heavily exposed men--results from a lack of talent or imagination. It is my hope that it results from the fact that exposure was not as widespread or intense as has been believed.

2. What does OTA consider the minimal criteria and documented correlation necessary for a veteran to be included as either an exposed or unexposed Vietnam veteran for the purposes of this study?

OTA has never independently developed exposure criteria for the Agent Orange study. The criteria settled upon by the Exposure Subpanel of the Agent Orange Working Group Science Panel are the best that I know of, representing a minimal acceptable exposure. At the time the subpanel was working, they were aware of the lack of evidence for exposure that CDC had come up against, and decisions were made to allow as "loose" a definition of exposure as possible without compromising the study entirely. The Subpanel suggested including individuals who were: 1) within 500 meters at the time of a herbicide application on at least one occasion; or 2) within 2 kilometers and 6 days of a spray at least 14 times. These criteria are much "looser" than are generally acceptable for occupational epidemiologic studies.

All attempts to define exposure to Agent Orange of necessity have relied to a large extent on informed judgment. The possibility of using a blood assay for dioxin to validate records-based exposures, as CDC proposed at this hearing, is attractive. To the extent that it is possible, the blood assay will enhance the validity of a records-based approach to the extent the two measures corroborate each other.

3. Does OTA have any recommendations concerning protocol and procedures used to identify study cohorts?

We have no specific recommendations.

4. Please elaborate on whether OTA's failure to approve CDC's protocol with regard to exposure means that it has concluded that there is no way military records alone can be used to determine exposure in the conduct of a scientifically valid Agent Orange study.

The information that has been extracted from military records concerning ground troops has proven insufficient for identifying men with significant exposure. I believe that the records research performed by the Environmental Support Group under the direction of the Exposure Subpanel was exhaustive and focused on battalions thought to be the most highly exposed. If other records come to light, particularly records of perimeter sprays, they might permit improved exposure classification. Currently, however, I do not believe that a study of ground troops can be conducted basing exposure estimates only on military records.